

National assessment of chemicals associated with coal seam gas extraction in Australia

Technical report number 13

Human health risks associated with surface handling of chemicals used in coal seam gas extraction in Australia: Appendix D – Risk assessment sheets

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Introduction

This Report: Human health risks associated with surface handling of chemicals used in coal seam gas extraction: Appendix D – Risk assessment sheets

This Appendix to the Human Health Risk Assessment report¹ contains individual human health risk assessments for a total of 69 drilling and hydraulic fracturing chemicals. The assessments of these chemicals cover risks to workers from occupational exposures and risks to the public from exposures from environmental contamination.

In addition to information on chemical identity and human health hazards, the assessment for each chemical, or groups of chemicals, contains a risk characterisation in which risks to human health from chemical exposures were estimated. Risk characterisation is the qualitative and, wherever possible, quantitative description of the likelihood of an agent or situation having the potential to cause adverse effects. Risk characterisation is conducted by integrating information on chemical hazard (toxicity) with information on exposure.

Each risk characterisation describes health risks associated with acute (single) as well as long-term (repeated) exposure for a number of relevant exposure scenarios. Risks from acute exposure are characterised qualitatively, whilst risks from long-term exposure are characterised quantitatively using a Margin of Exposure (MOE) methodology. Details on the methodology used for risk characterisation are available in the human health risk assessment report (NICNAS 2017a).

A logical consequence of this process of characterising health risks is the application of the information to develop practical measures to protect human health. Accordingly, in addition to a risk characterisation, each risk assessment describes measures available to mitigate identified human health risks.

¹ NICNAS 2017a, *Human health risks associated with surface handling of chemicals used in coal seam gas extraction*, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

D1 Boric acid (H_3BO_3)

CAS RN	CAS Name
10043-35-3	Boric acid (H_3BO_3)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

1.1 Chemical use and concentration

The document from here on refers to CAS RN 10043-35-3 as Boric Acid, one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a crosslinker. Another function of the chemical is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 800 g/kg (80%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.216 g/L (0.022%).

1.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Hazard information was obtained from the following comprehensive reviews of boron and its compounds – World Health Organisation (WHO 1998), United States Environment Protection Agency (US EPA 2004), Agency for Toxic Substances and Disease Registry (ATSDR 2010), European Chemicals Agency (ECHA 2010) and the Netherlands National Institute for Public Health and the Environment (RIVM 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The hazard assessment of boric acid was conducted as a group assessment of three substances - boric acid (H_3BO_3), boron sodium oxide ($\text{B}_8\text{Na}_2\text{O}_{13}$) (more commonly referred to as boric acid disodium salt) and borax ($\text{Na}_2(\text{B}_4\text{O}_7) \cdot 10\text{H}_2\text{O}$).

In physiological conditions, aqueous solutions of simple borates will exist predominantly as un-dissociated boric acid. Therefore, the chemical and toxicological properties of simple borates such as boric acid, boric acid disodium salt and borax are expected to be similar on a mol boron/L equivalent basis when dissolved in water or biological fluids at the same pH and low concentration. Accordingly, read-across of toxicity testing results between these borate species and from other similar borate species differing only in extent of hydration was applied, and testing results were expressed as boron equivalents.

Toxicity testing was conducted on several borate compounds. Borates were found to be of low acute toxicity and low skin irritation potential. Mild eye irritation observed in animal studies may be due to the crystalline nature of the compounds tested. In inhalation testing in animals with boric acid aerosols, borates were found to be sensory irritants. Sensory irritation

from inhalation of borates as dusts has also been documented in humans, with a No-Observed-Adverse-Effect-Concentration (NOAEC) of 0.8 mg boron/m³ identified for worker exposures (ECHA 2009).

Borates were shown not to be skin sensitisers, genotoxic or carcinogenic.

Repeated exposures to boron as boric acid induced effects on fertility (testicular toxicity), development and the blood system. The No Observed Adverse Effect Level (NOAEL) for effects on male fertility and the blood system (haemotoxicity) was 17.5 mg boron/kg bw/day with a Lowest Observed Adverse Effect-Level (LOAEL) of 58.5 mg boron/kg bw/day. This NOAEL was the equivalent of 100 mg boric acid/kg bw/day.

The most sensitive endpoint was developmental toxicity (foetal development), with a NOAEL of 9.6 mg boron/kg bw/day. The LOAEL was 13.3 mg boron/kg bw/day. This NOAEL was the equivalent of 55 mg boric acid/kg bw/day.

1.3 Human exposure assessment

1.3.1 Worker exposure

Exposure of workers to boric acid is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual boric acid.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented, occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.1) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.1 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	2.40 x 10 ⁻³	2.10 x 10 ⁻²	2.34 x 10 ⁻²
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Cleaning and maintenance (hydraulic fracturing)	1.30×10^{-5}	2.26×10^{-5}	3.56×10^{-5}
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			2.34×10^{-2}
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017c).

1.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from a storage tank or pond at operational sites and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface

water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.2) and children (Table D.3).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.2 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	26.712	N/A	26.712
Bathing in contaminated surface water	Negligible*	7.93 x 10 ⁻⁵	7.93 x 10 ⁻⁵
Swimming in contaminated surface water	1.98 x 10 ⁻³	7.93 x 10 ⁻⁵	2.06 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			26.714
Bulk spill from a surface storage tank or pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.088	N/A	0.088
Bathing in contaminated groundwater	Negligible*	2.44 x 10 ⁻⁷	2.44 x 10 ⁻⁷
Drinking contaminated surface water	1.60 x 10 ⁻⁵	N/A	1.60 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	4.44 x 10 ⁻¹¹	4.44 x 10 ⁻¹¹
Swimming in contaminated surface water	1.19 x 10 ⁻⁹	4.74 x 10 ⁻¹¹	1.23 x 10 ⁻⁹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.088
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			1.60 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017b). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.3 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	93.492	N/A	93.492
Bathing in contaminated surface water	Negligible*	1.38 x 10 ⁻⁴	1.38 x 10 ⁻⁴
Swimming in contaminated surface water	2.77 x 10 ⁻²	1.47 x 10 ⁻⁴	2.79 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			93.520
Bulk spill from a surface storage tank or pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.308	N/A	0.308
Bathing in contaminated groundwater	Negligible*	4.53 x 10 ⁻⁷	4.53 x 10 ⁻⁷
Drinking contaminated surface water	5.59 x 10 ⁻⁵	N/A	5.59 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	8.24 x 10 ⁻¹¹	8.24 x 10 ⁻¹¹
Swimming in contaminated surface water	1.66 x 10 ⁻⁸	8.80 x 10 ⁻¹¹	1.67 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.308
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			5.60 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017b). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

1.4 Human health risk characterisation

1.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

1.4.2 Occupational health risks

1.4.2.1 Acute health risks

Health effects information indicates that acute exposure to boric acid via the dermal route is unlikely to result in adverse health effects. However, inhalation toxicity testing in animals with borate aerosols and documented episodes of worker exposures to borate dusts indicate that inhalation of boric acid in the workplace under certain circumstances will result in sensory irritation.

For hydraulic fracturing operations, boric acid as delivered to operational sites is in solid form. No workplace monitoring data are available for hydraulic fracturing operations to indicate levels of borate dusts during these operations. However, if borate dusts are generated, sensory irritation may occur, depending on the level of worker exposure.

In general, acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

Boric acid is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the much lower concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids represents a much lower acute health risk for workers compared to handling the chemical as delivered to operational sites.

1.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is developmental toxicity (foetal development). The NOAEL established for this effect is 55 mg boric acid/kg bw/day. This health effect is identified from prenatal developmental toxicity testing in animals and is not relevant for non-pregnant workers. The most sensitive, relevant health effect for male and non-pregnant female workers is effects on the blood system (haemotoxicity), for which a NOAEL was established at 100 mg/kg bw/day. Effects on fertility (testes), additionally relevant for male workers, were also observed at this dose.

Margins of Exposure (MOEs) for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.4). For the purposes of this risk assessment, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity/testicular toxicity.

Table D.4 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	2 355** / 4 282***
Cleaning and maintenance (hydraulic fracturing)	1.55 x 10 ⁶ ** / 2.81 x 10 ⁶ ***
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	2 352** / 4 276***

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.1). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/testicular toxicity.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the lower concentration of the chemical in hydraulic fracturing fluids, repeated exposure to the chemical via these fluids is also of low concern for workers.

1.4.3 Public health risks

1.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

1.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects of developmental toxicity (foetal development) and haemotoxicity/testicular toxicity and NOAELs established for these different effects, MOEs were calculated for adults and children for various exposure scenarios (Table D.5).

Table D.5 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2** 4***	N/A** 1***
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater	625** 1136***	N/A** 325***

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
plus swimming in contaminated surface water		
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	3.44 x 10 ^{6**} 6.26 x 10 ^{6***}	N/A** 1.79 x 10 ^{6***}

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.2 and Table D.3). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/testicular toxicity. N/A The consideration of developmental toxicity (foetal development) is not relevant for children and so MOEs for this health effect were not calculated for children.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures based on the modelled exposure scenario of a bulk spill from a transport accident.

For this bulk spill scenario, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity/testicular toxicity. For adults, the MOEs for this exposure scenario suggest that the chemical posed a potential concern for developmental toxicity and haemotoxicity/testicular toxicity. For children, developmental toxicity (foetal development) is not relevant and therefore MOEs for this effect were not calculated. However, the calculated MOE based on haemotoxicity/testicular toxicity is suggestive of a potential concern for children.

In contrast, the chemical is of low concern for either adults or children based on the modelled exposure scenario of a long-term subsurface leak from a produced water storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

1.4.4 Conclusions

1.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of low concern for acute adverse health effects for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for acute adverse health effects for workers.

Calculated MOEs indicate that the chemical is of low concern for chronic adverse health effects for workers from repeated exposures during operations.

1.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites, and so the chemical in this form is of low concern for acute adverse health effects for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggested a potential concern for adults and children based on certain modelled exposure scenarios. For the bulk spill scenario, calculated MOEs suggested a potential for developmental toxicity (foetal development) for pregnant adults and haemotoxicity/testicular toxicity for adults and children. However, these public health risks were estimated using conservative exposure modelling and are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

1.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

1.5.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

1.5.2 *Control measures available to minimise risks to the public*

1.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

1.6 References

- ATSDR (2010) Toxicological Profile for Boron. Agency for Toxic Substances and Disease Registry (ATSDR), United States Department of Health and Human Services. Accessed November 2010.
- ECHA (2009) Boric acid (Boric acid crude natural) Annex XV Transitional Report. Documentation of the work under the Existing Substance Regulation (EEC) No 793/93 and submitted to the European Chemicals Agency according to Article 136(3) of Regulation (EC) No 1907/2006.
- ECHA (2010) Annex 1 to the opinion on new scientific evidence on the use of boric acid and borates in photographic applications by consumers. Background document. European Chemicals Agency (ECHA) Committee for Risk Assessment (RAC). Adopted 29 April 2010.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- RIVM (2013) CLH Report. Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance Name: Disodiumoctaborate anhydrate. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) (The Netherlands National Institute for Public Health and the Environment) March 2013.
- US EPA (2004) Toxicological review of boron and compounds (CAS 7440-42-8). In support of Summary Information on the Integrated Risk Information System (IRIS) June 2004 US Environmental Protection Agency (US EPA), Washington DC.
- World Health Organisation (WHO) (1998) International Programme on Chemical Safety.(IPCS) Environmental Health Criteria 204, Boron. World Health Organisation, IPCS Working Group, 1998.

D2 Calcium chloride

CAS RN	CAS Name
10043-52-4	Calcium chloride

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

2.1 Chemical use and concentration

Calcium chloride is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

2.2 Critical health effects

Adverse effects of calcium chloride on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The following health hazard information is derived from the Organisation for Economic Co-operation and Development Screening Information Dataset Initial Assessment Report on calcium chloride (OECD 2002) and a European Union Registration, Evaluation, Authorisation and Restriction of Chemicals dossier (REACH 2013).

Calcium chloride has low acute oral and dermal toxicity. The oral and dermal median lethal dose (LD50) values for calcium chloride are > 2 000 mg/kg bw. Information on acute inhalation toxicity is not available. It is slightly irritating to the skin and severely irritating to the eye. Observations in humans suggest that calcium chloride may be a slight respiratory irritant. It is not a skin sensitiser.

From limited repeat dose data in rats, intakes of up to 2000 mg/kg bw/day via diet were without effect. Calcium chloride is neither genotoxic nor carcinogenic, nor a developmental toxicant.

In the absence of an appropriate No-Observed-Adverse-Effect Level (NOAEL), the highest dose tested in the oral study (2 000 mg/kg bw/day) is used for human health risk assessment.

2.3 Human exposure assessment

2.3.1 Worker exposure

Exposure of workers to calcium chloride is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual calcium chloride.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented, occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.6) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.6 Internal doses resulting from calcium chloride exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; E_{inh} – internal dose from inhalation exposure; E_{total} – total internal dose from all routes; n.d. – not disclosed.

* In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

2.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised calcium chloride solutions to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to calcium chloride via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.7) and children (Table D.8).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.7 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use			n.d.
Drinking, bathing and swimming in contaminated			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water			
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017b). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.8 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking and bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

2.4 Human health risk characterisation

2.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

2.4.2 Occupational health risks

2.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the very dilute solutions of calcium chloride as delivered to the site is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for acute adverse effects for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

Calcium chloride is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the even lower concentration in

hydraulic fracturing fluids, exposure to the chemical via these fluids is also of low concern for acute health effects for workers.

2.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 2 000 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.9).

Table D.9 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. *MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.6). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.*

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that calcium chloride is of low concern for workers from repeated exposures during certain operations.

2.4.3 Public health risks

2.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

2.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

MOEs were calculated for adults and children for various exposure scenarios based on the highest dose without any adverse effect (Table D.10).

Table D.10 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)**	Margin of Exposure (MOE) (CHILDREN)**
<i>Accidental bulk spill and surface runoff</i>		
Combined exposure from bulk spill – surface water	n.d.	n.d.

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)**	Margin of Exposure (MOE) (CHILDREN)**
use Drinking, bathing and swimming in contaminated surface water		
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking, bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.7 and Table D.8). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.*

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs indicate that calcium chloride is of low concern for adults and children from repeated exposures based on the modelled exposure scenarios.

2.4.4 Conclusions

2.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, calcium chloride, as delivered to operational sites, is of low concern for acute adverse health effects for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for acute adverse health effects for workers.

Calculated MOEs indicate that the chemical is of low concern for chronic adverse health effects for workers from repeated exposures during operations.

2.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical in concentrated form and so the chemical is of low concern for acute adverse health effects.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults and children based on certain modelled exposure scenarios.

2.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

2.5.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

2.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2002) Screening Information Dataset (SIDS) Initial Assessment Report for SIAM 15. calcium chloride. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database.
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D3 Ethanol, 2,2',2''-nitrilotris-

CAS RN	CAS Name
102-71-6	Ethanol, 2,2',2''-nitrilotris-

3.1 Chemical use and concentration

The document from here on refers to Ethanol, 2,2',2''-nitrilotris- (CAS RN 102-71-6) as 'triethanolamine', one of the synonyms of the chemical.

Triethanolamine is noted on Australian industry websites as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is for gel management.

No identity or concentration data were provided for triethanolamine in submissions to an industry survey of chemicals used for coal seam gas extraction in Australia (NICNAS 2017c). A safety data sheet for a Schlumberger product J318, typically used as a liquid breaker aid for hydraulic fracturing in Australia (QGC 2014), lists triethanolamine present at a concentration of 60-100%. Thus, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled in its pure form as a liquid product at a concentration of 1 000 g/L (100%).

No data were provided in the industry survey for the final concentration of triethanolamine in hydraulic fracturing fluid. An Australia Pacific Liquid Natural Gas (APLNG) factsheet listed the range of concentrations of the chemicals used in gel / viscosity management from 0 to 0.25% (APLNG 2014). For the purposes of this risk assessment, triethanolamine is assumed to be present in hydraulic fracturing fluids prior to injection at a concentration of 2.5 g/L (0.25%).

3.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazard was obtained predominantly from the Organisation for Economic Co-operation and Development (OECD 2001) and the Registration, Evaluation, Authorisation and Restriction of Chemicals dossier of the chemical (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Triethanolamine has low acute oral and dermal toxicity but may cause eye and respiratory irritation. Triethanolamine was non-irritating to the skin in rabbit studies, whilst studies in humans indicate that the chemical can cause skin irritation. The chemical is not a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment is 125 mg/kg bw/day based on systemic effects involving changes in bodyweight and organ to bodyweight ratios.

The chemical is neither genotoxic nor carcinogenic, and it is not a reproductive toxicant.

3.3 Human exposure assessment

3.3.1 Worker exposure

Exposure of workers to triethanolamine is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/ aerosols during operations. Exposure may also occur from contact with produced water containing residual triethanolamine.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented, occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.11) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.11 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.600	0.080	0.680
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.030	0.001	0.031
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.711
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; E_{inh} – internal dose from inhalation exposure; E_{total} – total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

3.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised/aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.12) and children (Table D.13).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.12 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.390	N/A	33.390
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻²	1.98 x 10 ⁻²
Swimming in contaminated surface water	2.48 x 10 ⁻³	1.98 x 10 ⁻²	2.23 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			33.432
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.019	N/A	1.019
Bathing in contaminated groundwater	Negligible*	5.66 x 10 ⁻⁴	5.66 x 10 ⁻⁴
Drinking contaminated surface water	1.85 x 10 ⁻⁴	N/A	1.85 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	1.03 x 10 ⁻⁷	1.03 x 10 ⁻⁷
Swimming in contaminated surface water	1.37 x 10 ⁻⁸	1.10 x 10 ⁻⁷	1.24 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.019
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			1.85 x 10 ⁻⁴

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.13 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻²	3.44 x 10 ⁻²
Swimming in contaminated surface water	3.47 x 10 ⁻²	3.68 x 10 ⁻²	7.15 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			116.971
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	3.565	N/A	3.565
Bathing in contaminated groundwater	Negligible*	1.05 x 10 ⁻³	1.05 x 10 ⁻³
Drinking contaminated surface water	6.48 x 10 ⁻⁴	N/A	6.48 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	1.91 x 10 ⁻⁷	1.91 x 10 ⁻⁷
Swimming in contaminated surface water	1.92 x 10 ⁻⁷	2.04 x 10 ⁻⁷	3.96 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			3.566
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			6.48 x 10 ⁻⁴

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

3.4 Human health risk characterisation

3.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies,

the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

3.4.2 Occupational health risks

3.4.2.1 Acute health risks

Health effects information indicates that acute exposures with the pure chemical will result in adverse health effects such as eye irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.25%), acute exposure to the chemical via these fluids is of low concern for workers.

3.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is systemic toxicity. The NOAEL established for this effect is 125 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.14).

Table D.14 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	184
Cleaning and maintenance (hydraulic fracturing)	4060
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	176

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.11).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in the hydraulic fracturing fluid produced water, repeated exposure to the chemical via these fluids is also of low concern for workers.

3.4.3 Public health risks

3.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for acute adverse health effects for the public.

3.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.15).

Table D.15 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	4	1
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	123	35
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	6.75×10^5	1.93×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.12 and Table D.13).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill, and for children from repeated exposures to contaminated groundwater from a leaking storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular

chemical would require more information to enable refined exposure estimates or environmental monitoring data.

3.4.4 Conclusions

3.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for acute adverse health effects for workers during operations based on the potential for eye irritation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for acute adverse health effects for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

3.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for acute adverse health effects for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggest a potential concern for adverse health effects, such as changes in bodyweight and organ to bodyweight ratios, for adults and children in the event of an accidental bulk spill and for children from exposure to contaminated groundwater from a leaking storage pond.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

3.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

3.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

3.5.2 Control measures available to minimise risks to the public

3.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

3.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

3.6 References

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<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D4 1,2-Ethanediol

CAS RN	CAS Name
107-21-1	1,2-Ethanediol

4.1 Chemical use and concentration

The document from here on refers to 1, 2-Ethanediol (CAS RN 107-21-1) as 'ethylene glycol', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a crosslinker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017a) is transported, stored and handled as a liquid at a concentration of 496 g/L (49.6%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.496 g/L (0.0496%).

4.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the World Health Organisation (WHO) (WHO 2002), National Toxicology Program Centre for the Evaluation of Risks to Human Reproduction (NTP-CERHR) (NTP-CERHR 2004), Organisation of Economic Co-operation and Development (OECD 2009), Agency for Toxic Substances and Disease Registry (ATSDR 2010), and Environment Canada / Health Canada (Environment Canada / Health Canada 2010).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Ethylene glycol demonstrates acute oral toxicity, is a mild skin and eye irritant, and a respiratory irritant in humans. The chemical is not a skin sensitiser.

Kidney effects are consistent adverse effects associated with repeated exposure to the chemical in animals, characterised by calcium oxalate crystal deposition and consequent renal lesions. The No-Observed-Adverse-Effect Level (NOAEL) is 150 mg/kg bw/day based on renal toxicity at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 300 mg/kg bw/day.

The chemical is not genotoxic or a carcinogen based on available data. Developmental effects (implant viability, weight of live fetuses, skeletal variations and / or malformations) were observed in animals, and were due to the accumulation of one of the chemical's metabolites, glycolic acid, which is also a relevant metabolic pathway in humans. From the evaluation of all available data from animal studies and *in vitro* metabolism studies, there is negligible concern of adverse developmental toxicity in humans from ethylene glycol at exposure levels below 125 mg/kg bw/day (NTP-CERHR 2004). This level is taken as the NOAEL for developmental toxicity in humans.

4.3 Human exposure assessment

4.3.1 Worker exposure

Exposure of workers to ethylene glycol is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual ethylene glycol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.16) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.16 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.298	0.016	0.314
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.006	6.588 x 10 ⁻⁵	0.006
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.320
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; E_{inh} – internal dose from inhalation exposure; E_{total} – total internal dose from all routes.

* In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

4.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.17) and children (Table D.18).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.17 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.055	N/A	3.055
Bathing in contaminated surface water	Negligible*	1.81 x 10 ⁻³	1.81 x 10 ⁻³
Swimming in contaminated surface water	2.27 x 10 ⁻⁴	1.81 x 10 ⁻³	2.04 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.059
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.202	N/A	0.202
Bathing in contaminated groundwater	Negligible*	1.12 x 10 ⁻⁴	1.12 x 10 ⁻⁴
Drinking contaminated surface water	3.67 x 10 ⁻⁵	N/A	3.67 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	2.04 x 10 ⁻⁸	2.04 x 10 ⁻⁸
Swimming in contaminated surface water	2.72 x 10 ⁻⁹	2.18 x 10 ⁻⁸	2.45 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.202
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			3.68 x 10 ⁻⁵

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.18 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.693	N/A	10.693
Bathing in contaminated surface water	Negligible*	3.15 x 10 ⁻³	3.15 x 10 ⁻³
Swimming in contaminated surface water	3.17 x 10 ⁻³	3.36 x 10 ⁻³	6.54 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			10.703
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.707	N/A	0.707
Bathing in contaminated groundwater	Negligible*	2.08 x 10 ⁻⁴	2.08 x 10 ⁻⁴
Drinking contaminated surface water	1.28 x 10 ⁻⁴	N/A	1.28 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	3.78 x 10 ⁻⁸	3.78 x 10 ⁻⁸
Swimming in contaminated surface water	3.81 x 10 ⁻⁸	4.04 x 10 ⁻⁸	7.85 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.708
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			1.29 x 10 ⁻⁴

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

4.4 Human health risk characterisation

4.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in this risk characterisation:

- where a NOAEL for humans was established, an MOE of less than 10 is considered a concern
- where a NOAEL was established from animal studies, an MOE of less than 100 is considered a concern.

4.4.2 Occupational health risks

4.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical is unlikely to result in acute adverse health effects. However, a clinical study showed respiratory irritation in humans from exposure to aerosolised ethylene glycol which may be relevant for workers. Therefore, the chemical is of potential concern for adverse health effects for workers from acute exposures.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

4.4.2.2 Long-term health risks

From the hazard characterisation, the most sensitive health endpoint for repeated exposures to the chemical is developmental toxicity (implant viability, weight of live foetuses, skeletal variations and / or malformations). The NOAEL established for this effect is 125 mg/kg bw/day in humans. This adverse health effect is identified from the evaluation of all available developmental toxicity data from animal studies and *in vitro* metabolism studies, and is not relevant for non-pregnant workers. The most sensitive, relevant adverse health effect for male and non-pregnant female workers is kidney effects, for which a NOAEL was established at 150 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for the developmental toxicity effect and kidney effect, with exposures estimated for different occupational activities and combined activities are presented in Table D.19 and Table D.20, respectively.

Table D.19 Margins of Exposure calculated for hydraulic fracturing occupational activities applicable for pregnant workers only

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	478
Cleaning and maintenance (hydraulic fracturing)	2.49 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	468

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.16).

Table D.20 Margins of Exposure calculated for hydraulic fracturing occupational activities applicable for male and non-pregnant female workers

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	398
Cleaning and maintenance (hydraulic fracturing)	2.08 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	390

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.16).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical, as delivered to operational sites, is of low concern for workers from repeated exposures during certain operations.

4.4.3 Public health risks

4.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

4.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the adverse health effects and NOAELs established for these effects, MOEs were calculated for pregnant individuals (Table D.21) and the general population (Table D.22) for various exposure scenarios.

Table D.21 Margins of Exposure calculated for different public exposure scenarios for pregnant individuals

Public exposure scenario*	Margin of Exposure (MOE) for pregnant individuals
Accidental bulk spill during transport and surface runoff	
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	41
Long-term subsurface leak from flowback and / or produced water storage pond	
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	618
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	3.40×10^6

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.17 and Table D.18).

Table D.22 Margins of Exposure calculated for different public exposure scenarios for the general population

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	49	14
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	742	212
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	4.08×10^6	1.17×10^6

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.17 and Table D.18).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs for pregnant individuals indicate that the chemical is of low concern for developmental toxicity from repeated exposures based on the modelled exposure scenarios. In contrast, the MOEs for the general population suggest a

potential concern for kidney effects for adults and children from repeated exposures to contaminated surface water following a transport spill.

It should be noted that while some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

4.4.4 Conclusions

4.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for acute health effects for workers during operations based on the potential for respiratory irritation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for acute health effects for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

4.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adverse developmental health effects for pregnant individuals. Calculated MOEs based on conservative Tier 1 exposure modelling are suggestive of a potential concern for kidney effects for the general population from repeated exposures to contaminated surface water following a transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

4.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

4.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant

state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

4.5.2 Control measures available to minimise risks to the public

4.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

4.6 References

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- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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WHO (2002) Ethylene Glycol: Human health aspects. Concise international chemical assessment document 45. World Health Organisation, Geneva.

D5 Ethanedial

CAS RN	CAS Name
107-22-2	Ethanedial

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

5.1 Chemical use and concentration

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final drilling fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a CBI concentration. After incorporation, it is present in drilling fluid at a CBI concentration.

5.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was sourced primarily from an Organisation for Economic Cooperation and Development (OECD) Screening Information Data Set Initial Assessment Report (OECD 2003), a World Health Organisation Concise International Chemical Assessment Document (WHO 2004), a European Commission Scientific Committee on Consumer Products report (European Commission 2005), and an industry dossier on ethanedial submitted under the Registration, Evaluation, Authorisation and Restriction of Chemicals program (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Ethanedial is moderately toxic via the oral and inhalation routes. In a guideline study in rats, an acute oral median lethal dose (LD₅₀) for a 40% ethanedial aqueous solution was reported at 3 300 mg/kg bw. This corresponds to 1 320 mg/kg bw day for the active ingredient. A median lethal concentration (LC₅₀) for inhalation toxicity was established at 2.44 g/L (active ingredient). Ethanedial is of low dermal toxicity.

Animal studies indicate that ethanedial is a skin and eye irritant. From both animal and human studies, ethanedial is also a skin sensitiser.

A single repeat dose inhalation toxicity study in rats revealed no systemic toxicity even at the highest dose of 10 mg/m³. From an oral 28-day repeat dose toxicity test conducted in accordance with OECD TG 407, a No-Observed-Adverse-Effect Level (NOAEL) was established at 40 mg/kg bw/day (active substance), based on dose related changes in body weight gain at higher doses. An adjustment factor of three is applied for inadequate duration of this study, as the no-effect dose was derived from a 28 - day study. Consequently, for the purposes of quantifying the health risk of the chemical, an adjusted NOAEL of 13.3 mg/kg bw/day is used in this risk assessment.

Ethanedial was shown to be mutagenic in both bacterial and mammalian cells *in vitro*. Unscheduled DNA synthesis was reported in one study in mice *in vivo*, but only within the pyloric sphincter and liver, and not in more remote organs.

Results from several carcinogenicity studies, tumour initiation/promotion studies and *in vitro* cell transformation assays show that ethanedial is not carcinogenic. Also, available data on ethanedial and an analogue of ethanedial present in aqueous solutions suggest no effects on fertility or developmental toxicity in the absence of maternal toxicity.

5.3 Human exposure assessment

5.3.1 Worker exposure

Exposure of workers to ethanedial is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols or particulates during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.23) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.23 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and			n.d.

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
maintenance (drilling)			
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; E_{inh} – internal dose from inhalation exposure; E_{total} – total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport of drilling muds are negligible (NICNAS 2017a).

5.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the aerosolised ethanedia/ particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to ethanedia via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.24) and children (Table D.25).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.24 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a)

Table D.25 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a)

5.4 Human health risk characterisation

5.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No other uncertainty factors are deemed necessary to account for the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

5.4.2 Occupational health risks

5.4.2.1 Acute health risks

Health effects information indicate that acute exposure to the pure chemical will result in adverse health effects, such as harm if inhaled, skin and eye irritation and skin sensitisation. However, given the concentration of the chemical as delivered to operational sites is less

than the default concentration cut-offs for the above acute adverse health effects, the chemical in this form is of low concern for acute adverse health effects for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance, and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, exposure to the chemical via these fluids is of low concern for acute health effects for workers.

5.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is systemic toxicity demonstrated by reduced bodyweight gain. The adjusted NOAEL established for these effects is 13.3 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the adjusted NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.26).

Table D.26 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	n.d.
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.23).*

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for systemic adverse health effects for workers from repeated exposures during certain operations.

5.4.3 Public health risks

5.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

5.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect of systemic toxicity for which an adjusted NOAEL of 13.3 mg/kg bw/day was established, MOEs were calculated for adults and children for various exposure scenarios (Table D.27).

Table D.27 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, this indicates that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

5.4.4 Conclusions

5.4.4.1 Occupational health risks

Despite the acute health hazards associated with the chemical, the chemical as delivered to operational sites is of low concern for workers during operations due to its low concentration.

Exposure to the substance via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposures to the chemical via drilling fluids are of low concern for workers.

5.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children, based on the modelled exposure scenarios.

5.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

5.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires an amendment to the current classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

5.5.2 Control measures available to minimise risks to the public

5.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before as well as during and after coal seam gas operations, would enhance the utility of such a program.

5.6 References

- ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation Version 2.1 November 2012. European Chemicals Agency.
- European Commission (2005) Scientific Committee on Consumer Products (SCCP). Opinion on Glyoxal.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

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REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on glyoxal. European Union. Accessed November 2013 at http://apps.echa.europa.eu/registered/data/dossiers/DISS-975ee9a4-211a-19c1-e044-00144f67d031/DISS-975ee9a4-211a-19c1-e044-00144f67d031_e044-00144f67d031_DISS-975ee9a4-211a-19c1-e044-00144f67d031.html

D6 2-Pentanone, 4-methyl-

CAS RN	CAS Name
108-10-1	2-Pentanone, 4-methyl-

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

6.1 Chemical use and concentration

The document from here on refers to 2-pentanone, 4-methyl- (CAS RN 108-10-1) as 'MIBK', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

6.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from a United States Environmental Protection Agency toxicological review of Methyl Isobutyl Ketone (US EPA 2003) and an Organisation for Economic Co-operation and Development SIDS Initial Assessment Report for Methyl Isobutyl Ketone (OECD 2011). Additional sources of hazard information for the chemical include the Registration Evaluation Authorisation of Chemicals dossier for the chemical (REACH 2013) and an International Agency for Research on Cancer monograph on Methyl Isobutyl Ketone (IARC 2012).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

In animals, MIBK is of low acute toxicity by the oral, dermal and inhalation routes. Reversible depressant effects on the central nervous system have been observed in humans after inhalation exposure and the chemical causes eye and respiratory tract irritation. Following repeated dermal application, flaking and drying of the skin could also occur but MIBK is not expected to be a sensitiser.

A number of effects suggestive of liver and kidney toxicity have been observed in animals following repeated oral exposures. The most appropriate No Observed Adverse Effect Level (NOAEL) for risk assessment determined from a 14-week inhalation study is 42 mg/kg bw/day based on liver and kidney effects in male rats at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 212 mg/kg bw/day.

MIBK is not genotoxic but there is sufficient evidence in rodents for the carcinogenicity of inhaled MIBK under conditions of repeated exposure at high dose levels, with the NOAEL equivalent to 763 mg/kg bw/day based on a LOAEL of 1525 mg/kg bw/day. The primary target organ for carcinogenicity was the kidney in rats and the liver in rats and mice.

Results of fertility and developmental toxicity studies in animals indicate that the chemical is not expected to be of concern. MIBK is foetotoxic at a Lowest-Observed-Adverse-Effect Concentration (LOAEC) of 3 000 ppm, where maternal toxicity is also evident, but is not a developmental toxicant at a No-Observed-Adverse-Effect Concentration (NOAEC) of 1 000 ppm.

6.3 Human exposure assessment

6.3.1 Worker exposure

Exposure of workers to MIBK is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised or volatilised chemical during operations. Exposure may also occur from contact with produced water containing residual MIBK.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.28) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.28 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; E_{inh} – internal dose from inhalation exposure; E_{total} – total internal dose from all routes; n.d. = not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

6.3.2 Public Exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals / aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.29) and children (Table D.30).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.29 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. = not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.30 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route; n.d. = not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

6.4 Human health risk characterisation

6.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

6.4.2 Occupational health risks

6.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as central nervous system effects via inhalation and eye and respiratory irritation. However, given the concentration of the chemical as delivered to operational sites is less than the default concentration cut-offs for the above acute adverse health effects, the chemical in this form is of low concern for acute adverse health effects for workers.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for acute health effects for workers.

6.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is systemic toxicity (liver and kidney toxicity). The NOAEL established for this effect is 42 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.31).

Table D.31 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.28).*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations. Given that the NOAEL for carcinogenic effects is at a higher dose (763 mg/kg bw/day) than for systemic effects, the chemical as delivered to operational sites is of low concern also for carcinogenic effects.

Given the low concentration of the chemical in hydraulic fracturing fluids, repeated exposure to the chemical via these fluids is also of low concern for workers.

6.4.3 Public health risks

6.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

6.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effect of liver and kidney toxicity for which a NOAEL of 42 mg/kg bw/day was established, MOEs were calculated for adults and children for various exposure scenarios (Table D.32).

Table D.32 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal. n.d. – not disclosed

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for systemic adverse health effects for adults or children from repeated exposures. For carcinogenic effects, for which the NOAEL is at a higher dose (763 mg/kg bw/day) than for systemic effects and the MOE is therefore > 100, there is also a low concern for adults or children.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure

scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

6.4.4 Conclusions

6.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of low concern for acute health effects for workers during operations.

Exposure to the substance via hydraulic fracturing fluids is of low concern for acute health effects for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

6.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

6.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

6.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires an amendment to the current classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

6.5.2 Control measures available to minimise risks to the public

6.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

6.6 References

- ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation Version 2.1 November 2012. European Chemicals Agency.
- IARC (2012) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans – Vol. 101 - Methyl Isobutyl Ketone. International Agency for Research on Cancer. Lyon, France: Accessed September, 2013 at: <http://monographs.iarc.fr/ENG/Monographs/vol101/mono101-006.pdf>.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2011) Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) for 2-Pentanone, 4-methyl- (108-10-1). Revised in November 2009. Accessed September, 2013 at: http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=053ed0d1-84b7-41ca-915f-2e009c49afe1&idx=0
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier for 2-Pentanone, 4-methyl- (CAS No: 108-10-1). European Union. Accessed September 2013 at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

US EPA (2003) Toxicological review of methyl isobutyl ketone (CAS RN 108-10-1). In support of Summary Information on the Integrated Risk Information System (IRIS) March 2003. U.S. Environmental Protection Agency (US EPA), Bathington DC.

D7 Pentanedral

CAS RN	CAS Name
111-30-8	Pentanedral

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

7.1 Chemical use and concentration

The document from here on refers to pentanedral (CAS RN 111-30-8) as 'glutaraldehyde', one of the synonyms of the chemical.

Glutaraldehyde is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within this fluid is confidential business information (CBI).

Prior to incorporation into the final drilling fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 300 g/L (30%). After incorporation, it is present in drilling fluid at a CBI concentration.

7.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

The information on health hazards was obtained from the Organisation for Economic Cooperation and Development (OECD 1995); Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers on glutaraldehyde (REACH 2013) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS 1994). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Glutaraldehyde has high acute oral and inhalation toxicity and low to moderate acute dermal toxicity. Based on human and animal data, it is corrosive, the vapours are irritating to the respiratory tract, and it has skin and respiratory sensitisation potential. Glutaraldehyde has high repeat dose oral and inhalation toxicity, with an oral No-Observed-Adverse-Effect Level (NOAEL) of 4 mg/kg bw/day based on changes in liver and kidney weights and clinical chemistry parameters. Glutaraldehyde is not genotoxic or carcinogenic. It did not have any adverse effects on the reproductive system of adult rats or on the development of foetuses.

The critical adverse health effects of glutaraldehyde are corrosivity, skin and respiratory tract sensitisation and acute and repeat dose oral and inhalation toxicity.

7.3 Human exposure assessment

7.3.1 Worker exposure

Exposure of workers to glutaraldehyde is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of the volatilised glutaraldehyde or its aerosols during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.33) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.33 Internal doses resulting from glutaraldehyde exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling	0.018	0.016	0.034
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - internal dose from dermal exposure; *E_{inh}* – internal dose from inhalation exposure; *E_{total}* – total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

7.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the volatilised glutaraldehyde to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to glutaraldehyde via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water for the different public exposure scenarios. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.34) and children (Table D.35).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.34 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	5.95 x 10 ⁻⁴	5.95 x 10 ⁻⁴
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	5.95 x 10 ⁻⁴	1.34 x 10 ⁻³
Combined exposure from bulk spill – surface water use			10.019
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

Table D.35 Internal doses for CHILDREN associated with drilling fracturing public exposure scenarios

Public exposure scenario	E_{oral} (mg/kg bw/day)	E_{derm} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.060	N/A	35.060
Bathing in contaminated surface water	Negligible*	1.03×10^{-3}	1.03×10^{-3}
Swimming in contaminated surface water	1.04×10^{-2}	1.10×10^{-3}	1.15×10^{-2}
Combined exposure from bulk spill – surface water use			35.072
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - internal dose from oral exposure; E_{derm} – internal dose from dermal exposure; E_{total} – total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

7.4 Human health risk characterisation

7.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

7.4.2 Occupational health risks

7.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site (300 g/L, 30%) is of potential concern for adverse health effects such as skin and eye damage and respiratory tract irritation. The chemical also has skin and respiratory sensitisation potential.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluid. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, acute exposure to the chemical via these fluids is of low concern for workers.

7.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures to the chemical are changes in clinical chemistry parameters and

relative organ (liver and kidney) weights. Glutaraldehyde has high repeat dose oral toxicity with an oral NOAEL of 4 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.36).

Table D.36 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	117
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.33).*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

7.4.3 Public Health Risks

7.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

7.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects for which a NOAEL of 4 mg/kg bw/day was established, MOEs were calculated for adults and children for various exposure scenarios (Table D.37).

Table D.37 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	0.4	0.1

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential

concern for adults and children from repeated exposures based on the modelled exposure scenarios.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

7.4.4 Conclusions

7.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for acute health effects for workers during operations based on the potential for skin and eye damage and respiratory tract irritation. The chemical also has skin and respiratory sensitisation potential.

Exposure to the chemical via drilling fluids is of low concern for acute health effects for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via drilling fluids is of low concern for workers.

7.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggested a potential concern (changes in clinical chemistry parameters and relative organ (liver and kidney) weights) for adults and children based on the modelled exposure scenario.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

7.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

7.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

7.5.2 Control measures available to minimise risks to the public

7.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

7.6 References

- NICNAS (1994) Glutaraldehyde. Priority Existing Chemical Assessment Report No. 3. National Industrial Chemicals assessment and Notification Scheme, Sydney.
http://www.nicnas.gov.au/__data/assets/pdf_file/0016/4363/PEC_3_Glutaraldehyde_Full_Report_PDF.pdf.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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D8 Ethanol, 2-butoxy-

CAS RN	CAS Name
111-76-2	Ethanol, 2-butoxy-

8.1 Chemical use and concentration

The document from here on refers to Ethanol, 2-butoxy- (CAS RN 111-76-2) as 'butoxyethanol', one of the synonyms of the chemical.

Butoxyethanol is noted on Australian industry websites as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its stated function within these fluids is as a surfactant.

No identity or concentration data were provided for butoxyethanol in submissions to an industry survey of chemicals used for coal seam gas extraction in Australia (NICNAS 2017b). Limited data were provided in supplementary industry information (NICNAS 2017b). A material safety data sheet (MSDS) for a surfactant/penetrating agent product PEN-88 HT typically used in deep hydraulic fracturing in Australia (Halliburton 2014a) lists butoxyethanol present at a concentration of 30-60%. Therefore, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled within a liquid product at a concentration of 600 g/L (60%).

No data were provided in the industry survey and only limited data were available in supplementary industry information for the final concentration of butoxyethanol in fluids used for hydraulic fracturing. Industry information indicates that the product PEN-88 HT containing butoxyethanol is used as an additive for acid injection treatments (Halliburton 2014b). These acid injection treatments, required to dissolve calcite in up to 10% of wells, are applied prior to the injection of hydraulic fracturing fluids. The fracturing fluids are then injected after the injected acid is removed from the well with a clean water flush (Santos 2010). The concentration of butoxyethanol in residual hydraulic fracturing fluids is then dependent on the extent to which residual acid containing butoxyethanol is mixed with fracturing fluids for storage and eventual disposal after completion of fracturing operations.

Due to the unavailability of detailed information on acid injection operations, the following calculations of butoxyethanol concentrations in flowback and / or produced water assume that all residual acid treatment chemicals, including butoxyethanol, are collected and mixed with other fluids from hydraulic fracturing operations for storage and treatment as flowback and / or produced water.

The concentration of butoxyethanol in flowback and / or produced water was estimated based on the following industry information for use of PEN-88 HT containing butoxyethanol (Halliburton 2014b):

- butoxyethanol present in PEN-88 HT at a maximum of 60%
- PEN-88 HT added to acid flush at a maximum of 5 US gallons (18.92 L) per 1 000 US gallons (3785 L)
- 5000 US gallons (18925 L) of acid flush injected prior to fracturing treatment
- a total volume of 230 000 L of hydraulic fracturing fluid (excluding acid flush) used per fracturing treatment (NICNAS 2017b).

Based on these assumptions, it is estimated that the amount of butoxyethanol compared to the total combined volume of injected acid flush/hydraulic fracturing fluids is 0.23 g/L (0.023%). This concentration is used for calculating public exposures from exposure scenarios involving leakage from flowback and / or produced water storage.

8.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazard was obtained predominantly from the United States National Institute for Occupational Safety and Health (NIOSH) (NIOSH 1990), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (NICNAS 1996), the European Union Risk Assessment Report (European Chemicals Bureau 2006), and the International Agency for Research on Cancer (IARC) monograph on butoxyethanol (IARC2006).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Butoxyethanol has low to moderate acute oral, dermal, and inhalation toxicity in animals. In humans, severe symptoms have been reported from acute ingestion of the chemical, suggesting a human Lowest Observed Adverse Effect Level (LOAEL) for acute effects (metabolic acidosis) of 400 mg/kg bw. The chemical is a skin irritant with occasional severe irritation reported in individual animals, and is moderately to severely irritating to the eyes. Butoxyethanol is not a skin sensitiser.

Repeat dose studies in a variety of animal species reveal haemotoxicity as a common effect following oral, dermal or inhalation exposures to butoxyethanol. For repeat oral dose toxicity, LOAELs of 69 and 82 mg/kg/day for male and female rats, respectively, were established and No Observed Adverse Effect Levels (NOAELs) were not established from this study. For repeat dermal dose toxicity, no systemic effects were observed at doses up to 150 mg/kg bw/day. For repeat inhalation dose toxicity, the established No-Observed-Adverse-Effect-Concentration (NOAEC) of 25 ppm (121 mg/m³), equivalent to an internal dose of 22.5 mg/kg bw/day, is used in the risk assessment.

The chemical is neither genotoxic nor carcinogenic. Reproductive studies revealed no direct effects of butoxyethanol on male or female reproduction in the absence of severe systemic toxicity. No developmental effects were noted in the absence of maternal toxicity.

8.3 Human exposure assessment

8.3.1 Worker exposure

Exposure of workers to butoxyethanol is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of the volatilised chemical/ aerosols during operations. Exposure may also occur from contact with produced water containing residual butoxyethanol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace

activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.38) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.38 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.108	0.028	0.136
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	8.28×10^{-4}	4.36×10^{-5}	8.71×10^{-4}
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.137
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

8.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)

- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised chemical/aerosol to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.39) and children (Table D.40).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.39 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	Eoral (mg/kg bw/day)	Ederm (mg/kg bw/day)	Ettotal (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	20.034	N/A	20.034
Bathing in contaminated surface water	Negligible*	3.57×10^{-3}	3.57×10^{-3}
Swimming in contaminated surface water	1.49×10^{-3}	3.57×10^{-3}	5.05×10^{-3}
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			20.043
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.094	N/A	0.094

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated groundwater	Negligible*	1.56 x 10 ⁻⁵	1.56 x 10 ⁻⁵
Drinking contaminated surface water	1.70 x 10 ⁻⁵	N/A	1.70 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	2.84 x 10 ⁻⁹	2.84 x 10 ⁻⁹
Swimming in contaminated surface water	1.26 x 10 ⁻⁹	3.03 x 10 ⁻⁹	4.29 x 10 ⁻⁹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.094
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; *E_{derm}* – Internal dose from dermal exposure; *E_{total}* – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.40 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	70.119	N/A	70.119
Bathing in contaminated surface water	Negligible*	6.19 x 10 ⁻³	6.19 x 10 ⁻³
Swimming in contaminated surface water	2.08 x 10 ⁻²	6.62 x 10 ⁻³	2.74 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			70.153
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.328	N/A	0.328
Bathing in contaminated groundwater	Negligible*	2.90 x 10 ⁻⁵	2.90 x 10 ⁻⁵
Drinking contaminated surface water	5.96 x 10 ⁻⁵	N/A	5.96 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	5.26 x 10 ⁻⁹	5.26 x 10 ⁻⁹

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Swimming in contaminated surface water	1.77 x 10 ⁻⁸	5.62 x 10 ⁻⁹	2.33 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.328
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			5.96 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

8.4 Human health risk characterisation

8.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

8.4.2 Occupational health risks

8.4.2.1 Acute health risks

Health effects information indicates that acute contact with the chemical as delivered to operational sites will result in adverse health effects such as dermal and inhalation toxicity, and skin and eye irritation. Therefore, the chemical is of potential concern for acute adverse health effects for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

8.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is haemotoxicity. The NOAEC established for this effect is 22.5 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.41).

Table D.41 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	165
Cleaning and maintenance (hydraulic fracturing)	2.58 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	164

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.38).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in hydraulic fluids, repeated exposure to the chemical via these fluids is of low concern for workers.

8.4.3 Public health risks

8.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

8.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.42).

Table D.42 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	1	0.3
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	240	69
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	1.32×10^6	3.78×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.39 and Table D.40).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures based on the modelled exposure scenario of a bulk transport spill. The MOEs are also suggestive of a potential concern for children based on the modelled exposure scenario of a long-term subsurface leak from a surface storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

8.4.4 Conclusions

8.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute dermal and inhalation toxicity, and skin and eye irritation.

Acute exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

8.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggested a potential concern for adults and children from repeated exposures from a bulk transport spill, and for children from repeated exposures from a leaking storage pond. However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

8.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

8.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

8.5.2 Control measures available to minimise risks to the public

8.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

8.5.2.2 Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program

8.6 References

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- IARC (2006) International Agency for Research on Cancer (IARC) Monograph Volume 88. 2-butoxyethanol.
- NICNAS (1996) 2-Butoxyethanol. Priority Existing Chemical Number 6, October 1996. Australian Government Publishing Service, Canberra.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals

Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NIOSH (National Institute for Occupational Safety and Health) (1990) Criteria for a Recommended Standard - Occupational Exposure to Ethylene Glycol Monobutyl Ether and Ethylene Glycol Monobutyl Ether Acetate. DHHS (NIOSH) Publication no.90-118, U.S. Department of Health and Human Services, Cincinnati, Ohio, USA, September 1990.

Santos (2010) Coal Seam Hydraulic Fracturing Fluid Environmental Risk Assessment. Golder Associates Report No. 107626105-001-R-Rev5. Accessed July 2014 at http://www.santos.com/library/Roma_Shallow_Gas_East_EMP_AppD.pdf

D9 Ethanol, 2-(2-ethoxyethoxy)-

CAS RN	CAS Name
111-90-0	Ethanol, 2-(2-ethoxyethoxy)-

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

9.1 Chemical use and concentration

The chemical, also known as diethylene glycol monoethyl ether and hereinafter referred to as DGEE, is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the physical form in which the chemical is transported, stored and handled was not reported in the coal seam gas industry survey (NICNAS 2017b). However, based on the published physical properties of the chemical (NICNAS 2017c), it is assumed that DGEE is delivered to site as a liquid. The chemical is transported at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

9.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from an Organisation for Economic Co-operation and Development assessment of the diethylene glycol ethers category (OECD 2007), the European Commission's Scientific Committee on Consumer Safety Opinion on Diethylene Glycol Monoethyl Ether (DEGEE) (SCCS 2013), and from a World Health Organisation Joint Expert Committee on Food Additives monograph on Diethylene Glycol Monoethyl Ether (WHO 2007).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

DGEE demonstrates low acute toxicity and is a mild eye irritant. The chemical is not a skin irritant or sensitiser. Based on a repeat dose study, it is likely to be a mild respiratory irritant.

Consistent adverse effects associated with repeated oral and dermal exposure to DGEE in animals are kidney and liver effects. The most appropriate No Observed Adverse Effect Level (NOAEL) for risk assessment determined from a 90-day gavage study in dogs is 400 mg/kg bw/day based on hepatic toxicity at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 1 000 mg/kg bw/day.

The chemical is not genotoxic, but no reliable studies were identified regarding carcinogenicity. The weight of evidence also indicates the chemical is not a reproductive or developmental toxicant – whilst a few studies indicated some minor effects, the vast majority of studies indicated no effects, even up to relatively high doses.

9.3 Human exposure assessment

9.3.1 Worker exposure

Exposure of workers to DGEE is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols or vapours during operations. Exposure may also occur from contact with produced water containing residual DGEE.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.43) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.43 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

9.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.44) and children (Table D.45).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.44 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak- groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak- surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.45 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak- groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak- surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

9.4 Human health risk characterisation

9.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra-species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

9.4.2 Occupational health risks

9.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for workers from acute exposures, particularly as it is delivered to the site significantly diluted.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of DGEE (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the even lower concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

9.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is liver toxicity. The NOAEL established for this effect is 400 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.46).

Table D.46 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.43).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in hydraulic fracturing fluids, repeated exposure to the chemical via these fluids is of low concern for workers.

9.4.3 Public health risks

9.4.3.1 Acute health risks

Given industrial use of DGEE for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

9.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.47).

Table D.47 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak–groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak–surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.44 and Table D.45).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

9.4.4 Conclusions

9.4.4.1 Occupational health risks

Given the lack of adverse health effects, the chemical as delivered to operational sites is of low concern for workers from acute exposures during operations.

Acute exposure to the chemical via hydraulic fracturing fluids or via produced water is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers for repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

9.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites, and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

9.5 Risk mitigation measures

As noted in the hazard assessment report (NICNAS 2017c), the chemical does not require classification as a workplace hazardous chemical.

Conservative (Tier 1) risk assessments indicate that the chemical is of low concern for workers and the public from use of the chemical in coal seam gas operations. No specific risk mitigation measures are therefore required. However, best practice chemical management should always be implemented to minimise human exposures.

9.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- OECD (2007) Screening Information Data Set (SIDS), Screening Initial Assessment Report (SIAR) for diethylene glycol ethers. Organisation for Economic Co-operation and Development (OECD), Paris. Accessed in August 2013 at <http://webnet.oecd.org/HPV/UI/handler.axd?id=9d4a3735-c227-46bc-8bc3-561e5486c9dc>
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http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_119.pdf

WHO (2007) FAO/WHO Joint Expert Committee on Food Additives; WHO Food Additives Series 30 Diethylene Glycol Monoethyl Ether. World Health Organisation, Geneva. Accessed in August 2013 at <http://www.inchem.org/pages/jecfa.html>

D10 Silica gel/Precipitated silica (SiO₂) and amorphous silica (crystalline free)

CAS Nos.	CAS Names
112926-00-8	Silica gel/Precipitated silica (SiO ₂)
7631-86-9	Amorphous silica (crystalline free)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

10.1 Chemical use and concentration

Amorphous silica, independent of its form and method of preparation, is found under the CAS RN 7631-86-9. To differentiate between the silica polymorphs, specific CAS registry numbers have been generated for each form of silica.

Commonly encountered amorphous silicas are Silica gel and Precipitated silica, and both bear the CAS RN 112926-00-8, but are differentiated according to their method of preparation.

While one company reported the use of amorphous silica under the general CAS number 7631-86-9 (polymorph not specified), others reported the names and CAS numbers of the specific polymorphs of amorphous silica. This report therefore assesses the risks of amorphous silica in general with specific toxicological data from studies conducted with silica gel/precipitated silica (CAS RN 112926-00-8). These two forms of synthetic amorphous silica have been specifically identified as being used in coal seam gas extraction in Australia.

The two forms of silica are used as components of hydraulic fracturing fluid formulations for coal seam gas extraction. Their function within the fluid is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, amorphous silica as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a suspension in the hydraulic fracturing product (concentration not provided, NICNAS therefore assumes a default maximum concentration of 100%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.0059 g/L (0.00059%).

Silica gel / Precipitated silica is transported, stored and handled as a dilute liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at an even more dilute CBI concentration.

10.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). Information on health hazards was obtained from the Organisation for Economic Co-operation and Development (OECD 2004) and the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC 2006)

reviews on amorphous silica. The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Amorphous silicas, including silica gel and precipitated silica, are regarded as having negligible absorption through oral and dermal routes, and are absorbed to a minute extent by inhalation. They have low acute toxicity. No mortalities were reported in acute oral, dermal or inhalation animal studies. They are not skin or eye irritants. Data on skin sensitisation potential of these chemicals are not available; however, based on their structure and physico-chemical properties, precipitated silica and silica gel are not likely to be skin sensitisers.

Repeated oral exposure to amorphous silica (including silica gel and precipitated silica) had no adverse effect up to a dose of 4 000 mg/kg. Similarly, in numerous inhalation studies, there were no significant adverse effects in rats exposed to up to 50 mg/m³ silica for three and eight months. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk, the highest dose tested in an eight - month inhalation study in rats (50 mg/m³) is used in this risk assessment, noting that this dose was associated with reversible local effects.

10.3 Human exposure assessment

10.3.1 Worker exposure

Exposure of workers to silica is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of particulates during hydraulic fracturing operations. Exposure may also occur from contact with produced water containing residual silica.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose was estimated using exposure modelling and inhalation absorption rates determined from the hazard characterisation. Further details on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, are available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

As absorption of all forms of silica through the skin is considered to be negligible, internal dose via the dermal route is considered as zero. On the basis of the reported dilution of the chemical used in the fracking fluid, combined with the 1% inhalation absorption rate, any absorption through the lungs will also be negligible. Total absorption of amorphous silica in workers handling the chemical is therefore considered negligible.

10.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of silica particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to silica via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. However, based on consideration of potential occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Modelling can be used to derive predicted environmental concentrations (PECs) for groundwater and surface water for the different public exposure scenarios. The total internal human dose can then be estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Since the oral and dermal absorption of all forms of silica are considered to be nil, exposure to silica through these two routes was not considered further.

Public exposure to silica by all three routes was therefore considered to be negligible.

10.4 Human health risk characterisation

10.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

10.4.1.1 Occupational health risks

10.4.1.2 Acute health risks

Health effects information indicates that acute exposure to pure silica is unlikely to result in adverse health effects. Therefore, acute exposure to these chemicals is of low concern for workers, even assuming the pure chemical is delivered to the operational site.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

10.4.1.3 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated inhalation exposures to precipitated silica at any dose tested, up to 50 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.48). Since the actual identity of the amorphous silica (CAS No 7631-86-9) is not known, data from the inhalation study with precipitated silica is used to characterise risk from amorphous silica.

Assuming an average rat weight of 350 g and a respiratory rate of 0.29 m³/day (Derelanko 2000), this represents an absorbed dose as shown in Equation D.1 below.

$$\frac{50\text{mg}/\text{m}^3 \times 0.29\text{m}^3/\text{day} \times 6\text{h}}{0.35\text{kg} \times 24\text{h}} = 10.4\text{ mg/kg bw/day} \quad [\text{Equation D.1}]$$

Table D.48 Margins of Exposure calculated for hydraulic fracturing occupational activities during hydraulic fracturing

Activity*	Margin of Exposure (MOE)**	
	Amorphous Silica	Silica Gel / Ppted Silica
Mixing/blending of hydraulic fracturing chemicals	3.9 x 10 ⁴	n.d.
Cleaning and maintenance (hydraulic fracturing)	1.7 x 10 ⁹	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	4.0 x 10 ⁴	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures. ** In the absence of a No-Observed-Adverse-Effect Level (NOAEL), these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in hydraulic fracturing fluids, repeated exposure to the chemical via these fluids is also of low concern for workers.

10.4.2 Public health risks

Due to the negligible absorption of silica by the oral and dermal routes and likely low public exposure to silica via ambient air, the risk to public health from exposure to amorphous silica (all polymorphs) is regarded as negligible, and therefore further risk characterisation has not been undertaken.

10.4.3 Conclusions

10.4.3.1 Occupational health risks

Given the lack of adverse health effects, amorphous silicas, including silica gel and precipitated silica, as delivered to operational sites, are of low concern for workers from acute exposures during operations.

Acute exposures to these amorphous forms of silica via hydraulic fracturing fluids are also of low concern for workers.

Calculated MOEs indicate that the silicas as delivered to operational sites are of low concern for workers from repeated exposures during operations. Also, repeated exposure to the silicas via hydraulic fracturing fluids water is of low concern for workers.

10.4.3.2 Public health risks

The public is unlikely to come into contact with the chemicals as delivered to operational sites and so the chemicals in this form are of low concern for the public.

Due to negligible absorption of amorphous silica, including silica gel and precipitated silica, through oral and dermal routes, combined with the likely low level of exposure to the public through ambient air, repeated exposure to silica via environmental contamination is of low concern for adults and children.

10.5 Risk mitigation measures

As noted in the hazard assessment report (NICNAS 2017c), the chemicals do not require classification as workplace hazardous chemicals.

Conservative (Tier 1) risk assessments indicated that the chemicals are of low concern for workers and the public for use of the chemicals in coal seam gas operations. No specific risk mitigation measures are therefore required. However, best practice chemical management should always be implemented to minimise human exposures.

10.6 References

Derelanko MJ (2000) Toxicologists Pocket Handbook. CRC Press, 2000. Dourson ML, Susan I, Felter P, and Robinson D (1996) Evolution of Science-Based Uncertainty Factors in Non-cancer Risk Assessment. Reg Toxicol Pharmacol 24:108-120.

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- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- OECD (2004) Screening Information Data Set (SIDS) Initial Assessment Report (SIAR), Synthetic Amorphous Silica and Silicates. Organisation for Economic Co-operation and Development (OECD), Paris. Accessed in September 2013 at <http://www.chem.unep.ch/irptc/sids/oecdids/Silicates.pdf>

D11 Boron sodium oxide ($B_8Na_2O_{13}$)

CAS RN	CAS Name
12008-41-2	Boron sodium oxide ($B_8Na_2O_{13}$)

11.1 Chemical use and concentration

The document from here on refers to CAS RN 12008-41-2 as boric acid disodium salt, one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a biocide and crosslinker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical is transported, stored and handled as a solid at a concentration of 1 000 g/kg (100%). After incorporation it is present in hydraulic fracturing fluid at a concentration of 10 g/L (1%).

11.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Hazard information was obtained from the following comprehensive reviews of boron and its compounds – World Health Organisation (WHO 1998), United States Environment Protection Agency (US EPA 2004), Agency for Toxic Substances and Disease Registry (ATDSR 2010), European Chemicals Agency (ECHA 2010) and the Netherlands National Institute for Public Health and the Environment (RIVM 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The hazard assessment of boric acid disodium salt was conducted as a group assessment of three substances – boric acid (H_3BO_3), boron sodium oxide ($B_8Na_2O_{13}$) (more commonly referred to as boric acid disodium salt) and borax ($Na_2(B_4O_7) \cdot 10H_2O$).

In physiological conditions, aqueous solutions of simple borates will exist predominantly as un-dissociated boric acid. Therefore, the chemical and toxicological properties of simple borates such as boric acid, boric acid disodium salt and borax are expected to be similar on a mol boron/L equivalent basis when dissolved in water or biological fluids at the same Ph and low concentration. Accordingly, read-across of toxicity testing results was applied between these borate species and from other similar borate species differing only in extent of hydration, and testing results were expressed as boron equivalents.

Toxicity testing was conducted on several borate compounds. Borates were found to be of low acute toxicity and low skin irritation potential. Mild eye irritation observed in animal studies may be due to the crystalline nature of the compounds tested. In inhalation testing in animals with boric acid aerosols, borates were found to be sensory irritants. Sensory irritation from inhalation of borates as dusts has also been documented in humans, with a No-Observed-Adverse-Effect-Concentration (NOAEC) of 0.8 mg boron/m³ identified for worker exposures (ECHA 2009).

Borates were shown not to be skin sensitisers, genotoxic or carcinogenic.

Repeated exposures to boron as boric acid induced effects on fertility (testicular toxicity), development and the blood system. The No Observed Adverse Effect Level (NOAEL) for effects on male fertility and the blood system (haemotoxicity) was 17.5 mg boron/kg bw/day with a Lowest-Observed-Adverse-Effect Level (LOAEL) of 58.5 mg boron/kg bw/day. This NOAEL was the equivalent of 69 mg boric acid disodium salt/kg bw/day.

The most sensitive endpoint was developmental toxicity (foetal development), with a NOAEL of 9.6 mg boron/kg bw/day. The LOAEL was 13.3 mg boron/kg bw/day. This NOAEL was the equivalent of 38 mg of boric acid disodium salt/kg bw/day.

11.3 Human exposure assessment

11.3.1 Worker exposure

Exposure of workers to boric acid disodium salt is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols or particulates during operations. Exposure may also occur from contact with produced water containing residual boric acid disodium salt.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.49) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.49 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.003	0.026	0.029
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	6.0x10 ⁻⁴	0.001	0.002
Combined exposure			0.031

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Mixing/blending and cleaning and maintenance (hydraulic fracturing)			
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

11.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.50) and children (Table D.51).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.50 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.390	N/A	33.390
Bathing in contaminated surface water	Negligible*	9.91 x 10 ⁻⁵	9.91 x 10 ⁻⁵
Swimming in contaminated surface water	2.48 x 10 ⁻³	9.91 x 10 ⁻⁵	2.58 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			33.393
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	4.074	N/A	4.074
Bathing in contaminated groundwater	Negligible*	1.13 x 10 ⁻⁵	1.13 x 10 ⁻⁵
Drinking contaminated surface water	7.40 x 10 ⁻⁴	N/A	7.40 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	2.06 x 10 ⁻⁹	2.06 x 10 ⁻⁹
Swimming in contaminated surface water	5.49 x 10 ⁻⁸	2.20 x 10 ⁻⁹	5.71 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			4.074
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			7.40 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017b). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.51 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	1.72 x 10 ⁻⁴	1.72 x 10 ⁻⁴
Swimming in contaminated surface water	3.47 x 10 ⁻²	1.84 x 10 ⁻⁴	3.49 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			116.900
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	14.26	N/A	14.26
Bathing in contaminated groundwater	Negligible*	2.10 x 10 ⁻⁵	2.10 x 10 ⁻⁵
Drinking contaminated surface water	2.59 x 10 ⁻³	N/A	2.59 x 10 ⁻³
Bathing in contaminated surface water	Negligible*	3.81 x 10 ⁻⁹	3.81 x 10 ⁻⁹
Swimming in contaminated surface water	7.69 x 10 ⁻⁷	4.07 x 10 ⁻⁹	7.73 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater / surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			14.260
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.59 x 10 ⁻³

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017b). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

11.4 Human health risk characterisation

11.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies,

the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

11.4.2 Occupational health risks

11.4.2.1 Acute health risks

Health effects information indicates that acute exposure to boric acid disodium salt via the dermal route is unlikely to result in adverse health effects. However, inhalation toxicity testing in animals with borate aerosols and documented episodes of worker exposures to borate dusts indicate that inhalation of boric acid and borates in the workplace under certain circumstances will result in sensory irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed. For hydraulic fracturing operations, boric acid disodium salt as delivered to operational sites is pure and in solid form. Borate dusts and borate aerosols generated during hydraulic fracturing operations may therefore cause sensory irritation depending on the level of worker exposure.

Boric acid disodium salt is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the much lower concentration in hydraulic fracturing fluids (1% as compared to 100% for the chemical as delivered to site), acute exposure to the chemical via these fluids represents a much lower health risk for workers compared to handling the chemical as delivered to operational sites.

11.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is developmental toxicity (foetal development). The NOAEL established for this effect is 38 mg boric acid disodium salt/kg bw/day. This health effect is identified from prenatal developmental toxicity testing in animals and is not relevant for non-pregnant workers. The most sensitive, relevant health effect for male and non-pregnant female workers is effects on the blood system (haemotoxicity), for which a NOAEL was established at 69 mg/kg bw/day. Effects on fertility (testes), additionally relevant for male workers, were also observed at this dose.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.52). For the purposes of this risk assessment, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity/testicular toxicity.

Table D.52 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	1 300** 2 360***
Cleaning and maintenance (hydraulic fracturing)	23 060** 41 870***
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	1 230** 2 240***

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.49). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/testicular toxicity.

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that boric acid disodium salt is of low concern for workers from repeated exposures during certain operations.

11.4.3 Public health risks

11.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

11.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects of developmental toxicity (foetal development) and haemotoxicity/testicular toxicity and NOAELs established for these different effects, MOEs were calculated for adults and children for various exposure scenarios (Table D.53).

Table D.53 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	1** 2***	N/A** 0.60***
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater	9** 17***	N/A** 5***

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
plus swimming in contaminated surface water		
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	5.13 x 10 ^{4**} 9.32 x 10 ^{4***}	N/A** 2.66 x 10 ^{4***}

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.50 and Table D.51). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/testicular toxicity. N/A The consideration of developmental toxicity (foetal development) is not relevant for children and so MOEs for this health effect were not calculated for children.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill and exposures to contaminated groundwater/surface water from a leaking storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

11.4.4 Conclusions

11.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on its sensory irritation property.

Acute exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that boric acid disodium salt is of low concern for workers for repeated exposures during operations.

11.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites, and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, MOEs based on conservative Tier 1 exposure modelling suggested a potential concern for adults and children based on certain modelled exposure scenarios.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

11.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

11.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

For chemicals with serious health effects potentially via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

11.5.2 Control measures available to minimise risks to the public

11.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

11.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.

- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

11.6 References

- ATSDR (2010) Toxicological Profile for Boron. Agency for Toxic Substances and Disease Registry (ATSDR), United States Department of Health and Human Services. Accessed November 2010.
- ECHA (2009) Boric acid (Boric acid crude natural) Annex XV Transitional Report. Documentation of the work under the Existing Substance Regulation (EEC) No 793/93 and submitted to the European Chemicals Agency according to Article 136(3) of Regulation (EC) No 1907/2006.
- ECHA (2010) Annex 1 to the opinion on new scientific evidence on the use of boric acid and borates in photographic applications by consumers. Background document. Committee for Risk Assessment (RAC). Adopted 29 April 2010.
- NICNAS (2017a) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- RIVM (2013) CLH Report. Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance Name: Disodium octaborate anhydrate. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) (The Netherlands National Institute for Public Health and the Environment) March 2013.
- US EPA (2004) Toxicological review of boron and compounds (CAS 7440-42-8). In support of Summary Information on the Integrated Risk Information System (IRIS) June 2004 US Environmental Protection Agency Bathington DC.
- OrganisationWHO (1998) International Programme on Chemical Safety. Environmental Health Criteria 204, Boron. World Health Organisation, IPCS Working Group, 1998.

D12 Borax ($\text{Na}_2(\text{B}_4\text{O}_7) \cdot 10\text{H}_2\text{O}$)

CAS RN	CAS Name
1303-96-4	Borax ($\text{Na}_2(\text{B}_4\text{O}_7) \cdot 10\text{H}_2\text{O}$)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

12.1 Chemical use and concentration

The document from here on refers to CAS RN 1303-96-4 as borax.

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final drilling fluid, the chemical is transported, stored and handled as a liquid at a concentration of up to 24 g/L (2.4%). After incorporation, it is present in drilling fluid at a CBI concentration.

The chemical is also used as a component of a hydraulic fracturing fluid formulation. Its function within these fluids is as a crosslinker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of up to 372 g/L (37.2%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.372 g/L (0.037%).

12.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Hazard information was obtained from the following comprehensive reviews of boron and its compounds – World Health Organisation (WHO) (WHO 1998), United States Environment Protection Agency (US EPA) (US EPA 2004), Agency for Toxic Substances and Disease Registry (ATSDR 2010), European Chemicals Agency (ECHA 2010) and the Netherlands National Institute for Public Health and the Environment (RIVM 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The hazard assessment of borax was conducted as a group assessment of three substances - boric acid (H_3BO_3), boron sodium oxide ($\text{B}_8\text{Na}_2\text{O}_{13}$) (more commonly referred to as boric acid disodium salt) and borax ($\text{Na}_2(\text{B}_4\text{O}_7) \cdot 10\text{H}_2\text{O}$).

In physiological conditions, aqueous solutions of simple borates will exist predominantly as un-dissociated boric acid. Therefore, the chemical and toxicological properties of simple borates such as boric acid, boric acid disodium salt and borax are expected to be similar on a mol boron/L equivalent basis when dissolved in water or biological fluids at the same pH and low concentration. Accordingly, read-across of toxicity testing results between these

borate species and from other similar borate species differing only in extent of hydration was applied and testing results were expressed as boron equivalents.

Toxicity testing was conducted on several borate compounds. Borates were found to be of low acute toxicity and low skin irritation potential. Mild eye irritation observed in animal studies may be due to the crystalline nature of the compounds tested. In inhalation testing in animals with boric acid aerosols, borates were found to be sensory irritants. Sensory irritation from inhalation of borates as dusts has also been documented in humans, with a No-Observed-Adverse-Effect-Concentration (NOAEC) of 0.8 mg boron/m³ identified for worker exposures (ECHA 2009).

Borates were shown not to be skin sensitisers, genotoxic or carcinogenic.

Repeated exposures to boron as borax induced effects on fertility (testes), development and the blood system. The No Observed Adverse Effect Level (NOAEL) for effects on fertility and the blood system (haemotoxicity) was 17.5 mg boron/kg bw/day with a Lowest-Observed-Adverse-Effect Level (LOAEL) of 58.5 mg boron/kg bw/day. This NOAEL was the equivalent of 155 mg borax/kg bw/day.

The most sensitive endpoint was developmental toxicity (foetal development) with a NOAEL of 9.6 mg boron/kg bw/day. The LOAEL was 13.3 mg boron/kg bw/day. This NOAEL was the equivalent of 85 mg borax/kg bw/day.

12.3 Human exposure assessment

12.3.1 Worker exposure

Exposure of workers to borax is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual borax.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for the use of borax in drilling and also in hydraulic fracturing.

Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.54) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling and hydraulic fracturing processes, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.54 Internal doses resulting from chemical exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Drilling			
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	7.20×10^{-5}	6.28×10^{-4}	7.00×10^{-4}
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*
Hydraulic fracturing			
Mixing/blending of hydraulic fracturing chemicals	1.11×10^{-3}	9.74×10^{-3}	0.011
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	2.23×10^{-5}	3.90×10^{-5}	6.13×10^{-5}
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.011
Drilling mud and produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

12.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)

- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for drilling and hydraulic fracturing for adults (Table D.55 and Table D.56, respectively) and children (Table D.57 and Table D.58, respectively).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.55 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.003	N/A	0.003
Bathing in contaminated surface water	Negligible*	9.91 x 10 ⁻⁹	9.91 x 10 ⁻⁹
Swimming in contaminated surface water	2.48 x 10 ⁻⁷	9.91 x 10 ⁻⁹	2.58 x 10 ⁻⁷
Combined exposure from bulk spill – surface water use			0.003
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.56 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E_{oral} (mg/kg bw/day)	E_{derm} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	2.291	N/A	2.291
Bathing in contaminated surface water	Negligible*	6.80×10^{-6}	6.80×10^{-6}
Swimming in contaminated surface water	1.70×10^{-4}	6.80×10^{-6}	1.77×10^{-4}
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			2.291
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.152	N/A	0.152
Bathing in contaminated groundwater	Negligible*	4.21×10^{-7}	4.21×10^{-7}
Drinking contaminated surface water	2.75×10^{-5}	N/A	2.75×10^{-5}
Bathing in contaminated surface water	Negligible*	7.65×10^{-11}	7.65×10^{-11}
Swimming in contaminated surface water	2.04×10^{-9}	8.17×10^{-11}	2.12×10^{-9}
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.152
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.75×10^{-5}

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.57 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.012	N/A	0.012
Bathing in contaminated surface water	Negligible*	1.72 x 10 ⁻⁸	1.72 x 10 ⁻⁸
Swimming in contaminated surface water	3.47 x 10 ⁻⁶	1.84 x 10 ⁻⁸	3.49 x 10 ⁻⁶
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.012

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.58 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	8.017	N/A	8.017
Bathing in contaminated surface water	Negligible*	1.18 x 10 ⁻⁵	1.18 x 10 ⁻⁵
Swimming in contaminated surface water	2.38 x 10 ⁻³	1.26 x 10 ⁻⁵	2.39 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			8.019
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.530	N/A	0.530
Bathing in contaminated groundwater	Negligible*	7.81 x 10 ⁻⁷	7.81 x 10 ⁻⁷
Drinking contaminated surface water	9.64 x 10 ⁻⁵	N/A	9.64 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.42 x 10 ⁻¹⁰	1.42 x 10 ⁻¹⁰
Swimming in contaminated surface water	2.86 x 10 ⁻⁸	1.52 x 10 ⁻¹⁰	2.87 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use			0.530

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			9.64 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

12.4 Human health risk characterisation

12.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- species and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

12.4.1.1 Occupational health risks

12.4.1.2 Acute health risks

Health effects information indicates that acute exposure to borax via oral or dermal routes is unlikely to result in acute adverse health effects. However, inhalation toxicity testing in animals with borate aerosols and documented episodes of worker exposures to borate dusts indicate that inhalation of borax in the workplace under certain circumstances will result in sensory irritation. The levels associated with such irritant effects have been documented for workers exposed to borate dusts.

For drilling and hydraulic fracturing operations, borax as delivered to operational sites is in liquid form. The impact of inhalation of borate dusts is therefore not relevant for these operations. No workplace monitoring data are available for drilling or hydraulic fracturing operations to indicate levels of borate aerosols during these operations. However, given sufficient exposure to borate aerosols, sensory irritation will result.

In general, acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

Borax is a component of both drilling fluids and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low final concentrations of borax in drilling and hydraulic fracturing fluids, acute exposure to the chemical via these fluids will pose less of a concern to workers than exposures via the chemical as delivered to operational sites.

12.4.1.3 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is developmental toxicity (foetal development). The NOAEL established for this effect is 55 mg boric acid/kg bw/day. This health effect is identified from prenatal developmental toxicity testing in animals and is not relevant for non-pregnant workers. The most sensitive, relevant health effect for male and non-pregnant female workers is effects on the blood system (haemotoxicity), for which a NOAEL was established at 155 mg/kg bw/day. Effects on fertility (testes) were also observed at this dose but this health effect is relevant for male, but not female, workers.

Margins of Exposure (MOE) for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.59). For the purposes of this risk assessment, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity.

Table D.59 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Drilling	
Mixing/blending of drilling chemicals	$1.21 \times 10^{5**}/2.21 \times 10^{5***}$
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.
Hydraulic fracturing	
Mixing/blending of hydraulic fracturing chemicals	$7.83 \times 10^{3**}/1.43 \times 10^{4***}$
Cleaning and maintenance (hydraulic fracturing)	$1.39 \times 10^{6**}/2.53 \times 10^{6***}$
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	$7.78 \times 10^{3**}/1.42 \times 10^{4***}$

n.d. – not disclosed. * MOEs for transport/storage, injection and drilling muds/produced water handling are not calculated due to negligible human exposures. ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

12.4.2 Public health risks

12.4.2.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

12.4.2.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects of developmental toxicity (foetal development) and haemotoxicity, and NOAELs established for these different effects, MOEs were calculated for adults and children for various exposure scenarios (Table D.60 and Table D.61).

Table D.60 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2.55 x 10 ^{4**} /4.64 x 10 ^{4***}	N/A**/1.33 x 10 ^{4***}

** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity. N/A The consideration of developmental toxicity (foetal development) is not relevant for children and so MOEs for this health effect were not calculated for children.

Table D.61 Margins of Exposure calculated for different hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	37**/68***	N/A**/19***
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	561**/ 1023***	N/A**/ 292***
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	3.09 x 10 ^{6**} / 5.63 x 10 ^{6***}	N/A**/ 1.61 x 10 ^{6***}

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.55 and Table D.56). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity. N/A The consideration of developmental toxicity (foetal development) is not relevant for children and so MOEs for this health effect were not calculated for children.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures based on the modelled exposure scenario of a bulk spill of chemical for use in hydraulic fracturing fluid from a transport accident.

For this bulk spill scenario, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity. For adults, the MOEs are suggestive of a potential concern for both developmental toxicity and haemotoxicity. For children, developmental toxicity (foetal development) is not relevant and therefore MOEs for this effect were not calculated. However, the calculated MOE based on haemotoxicity is suggestive of a potential concern for this effect in children.

In contrast, the chemical is unlikely to pose a risk of adverse health effects for either adults or children based on the modelled exposure scenario of a long-term subsurface leak from a produced water storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

12.4.3 Conclusions

12.4.3.1 Occupational health risks

The chemical as delivered to operational sites is of low concern for workers during operations.

Acute exposure to the chemical via drilling/hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

12.4.3.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults and children for exposures to hydraulic fracturing fluid from a leaking storage pond and transport spills of the chemical for use in drilling fluids. For the scenario involving a transport spill of the chemical for use in fracturing fluids, calculated MOEs are suggestive of a potential concern for developmental toxicity (foetal development) for pregnant adults and haemotoxicity for adults and children.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

12.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

12.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

12.5.2 Control measures available to minimise risks to the public

12.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

12.6 References

- ATSDR (2010) Toxicological Profile for Boron. Agency for Toxic Substances and Disease Registry (ATSDR), United States Department of Health and Human Services. Accessed November 2010.
- ECHA (2009) Boric acid (Boric acid crude natural) Annex XV Transitional Report. Documentation of the work under the Existing Substance Regulation (EEC) No 793/93 and submitted to the European Chemicals Agency (ECHA) according to Article 136(3) of Regulation (EC) No 1907/2006.
- ECHA) (2010) Annex 1 to the opinion on new scientific evidence on the use of boric acid and borates in photographic applications by consumers. Background document. Committee for Risk Assessment (RAC). Adopted 29 April 2010.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National

Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia,
Commonwealth of Australia, Canberra.

NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

RIVM (2013) CLH Report. Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2. Substance Name: Disodiumoctaborate anhydrate. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) (The Netherlands National Institute for Public Health and the Environment) March 2013.

US EPA (2004) Toxicological review of boron and compounds (CAS 7440-42-8). In support of Summary Information on the Integrated Risk Information System (IRIS) June 2004 US Environmental Protection Agency (US EPA) Bathington DC.

OrganisationWHO (1998) International Programme on Chemical Safety. Environmental Health Criteria 204, Boron. World Health Organisation (WHO), IPCS Working Group, 1998.

D13 Calcium hydroxide

CAS RN	CAS Name
1305-62-0	Calcium hydroxide

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

13.1 Chemical use and concentration

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final drilling fluid, the chemical is transported, stored and handled as a solid at a concentration of 1 000 g/kg (100%). After incorporation, it is present in drilling fluid at a CBI concentration.

13.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

When systemically absorbed, calcium hydroxide dissociates into calcium ions and hydroxide ions. These are normal physiological components in humans subject to homeostatic mechanisms to regulate their levels. Hydroxide ions are a natural constituent of aqueous solutions arising from the self-ionisation reaction of water. Uptake of hydroxide ions has the potential to increase the pH of the blood. However, blood pH is efficiently regulated by mechanisms such as urinary excretion of bicarbonate and exhalation of carbon dioxide. Calcium is an abundant mineral in the body with a number of important functions including bone mineralisation, blood clotting and neuromuscular function. Ingested calcium hydroxide is subject to neutralisation under the acidic conditions of the stomach.

Calcium hydroxide has low acute oral and dermal toxicity. It is a moderate skin irritant and a severe eye irritant. Epidemiological studies indicate that calcium hydroxide is also a respiratory irritant. Calcium hydroxide is not genotoxic or carcinogenic and does not have any developmental effects in animals.

Oral or dermal repeat dose studies are not available for calcium hydroxide. In an epidemiological study, no significant adverse effects were observed in lime-kiln workers exposed to 1.2 mg/m³ lime dust (calcium oxide and calcium hydroxide). This atmospheric concentration was taken as an overall No-Observed-Adverse-Effect-Concentration (NOAEC) for calcium hydroxide and is used in this human health risk assessment. However, it should be noted that as this NOAEC represents an atmospheric concentration of the chemical in a workplace, the NOAEC value is likely to be conservative compared to a level that might be determined from laboratory studies.

Apart from non-specific effects such as alkalosis which may occur at high doses, systemic health effects from repeated exposures to calcium hydroxide are unlikely.

The critical adverse health effects of calcium hydroxide are skin, eye and respiratory tract irritation.

13.3 Human exposure assessment

13.3.1 Worker exposure

Exposure of workers to calcium hydroxide is possible via inadvertent spills and leaks, especially during any required manual handling, and via particulates during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.62) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.62 Internal doses resulting from calcium hydroxide exposures associated with drilling occupational activities

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0	0.026	0.026
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} – Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

13.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of calcium hydroxide particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to calcium hydroxide via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.63) and children (Table D.64).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.63 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.390	N/A	33.390
Bathing in contaminated surface water	Negligible*	0.0	0.0
Swimming in contaminated surface water	2.48 x 10 ⁻³	0.0	2.48 x 10 ⁻³
Combined exposure from bulk spill – surface water use			33.393
Drinking, bathing and swimming in contaminated			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

Table D.64 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	0.0	0.0
Swimming in contaminated surface water	3.47 x 10 ⁻²	0.0	3.47 x 10 ⁻²
Combined exposure from bulk spill – surface water use			116.900
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

13.4 Human health risk characterisation

13.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, a conservative NOAEC from a human study was used for human health risk assessment. Consequently, an uncertainty factor of only 10 (intra-species variation only) is applied in the MOE calculation, and an MOE of less than 10 is considered a concern.

13.4.2 Occupational health risks

13.4.2.1 Acute health risks

Health effects information indicates that acute exposure to calcium hydroxide as delivered to the site (100% pure chemical as a solid) will result in adverse health effects such as skin, eye and respiratory irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemicals (if required) and during manipulation of equipment containing the residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary

depending on work practices. In particular, given the significant damage the chemical can inflict on the eyes, acute exposure to the chemical via drilling fluids may still pose a potential concern for workers despite its low concentration in drilling fluids.

13.4.2.2 Long-term health risks

Studies on long-term adverse health effects by exposure via oral or dermal routes are not available. The European Union Scientific Committee on Occupational Exposure Limits for calcium oxide and calcium hydroxide reviewed an epidemiological study on the effects of occupational exposure to calcium oxide (SCOEL 2008). In this study, no significant adverse effects were observed in lime-kiln workers exposed to 1.2 mg/m³ lime dust (calcium oxide and calcium hydroxide). This atmospheric concentration was considered as an overall NOAEC for calcium hydroxide for the purpose of human health risk assessment.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.65).

Assuming 100% inhalation absorption, an average worker body weight of 70 kg, and a respiratory rate of 20 m³ of air (CalEPA 1997), this represents an internal absorbed dose as described in Equation D.2 below.

$$\frac{1.2 \text{ mg/m}^3 \times 20^3 \text{ /day} \times 8h}{70 \text{ kg} \times 24h} = 0.114 \text{ mg/kg bw/day} \quad [\text{Equation D.2}]$$

Again, it is emphasised that as this highest no-effect dose is derived from a NOAEC that itself represents a very conservative No-Adverse-Effects Level, the MOE calculation are also very conservative estimates of the safety of the exposure as compared to the no-concern MOE of 10.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the internal absorbed dose with exposures estimated for different occupational activities during drilling (Table D.65).

Table D.65 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of drilling fluids	5
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.62). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

In light of uncertainty factors derived for this risk characterisation and the use of an epidemiological study in which the mean atmospheric concentration of lime dust associated with adverse effects could not be ascertained, the calculated MOEs indicate that a potential concern for systemic adverse health effects cannot be ruled out for workers from repeated exposures during the modelled operations.

However, as noted, calcium hydroxide dissociates into calcium ions and hydroxide ions which are normal physiological components in humans and subject to homeostatic mechanisms to regulate their levels. Therefore, systemic health effects in workers from repeated exposures to calcium hydroxide are unlikely and the chemical is of low concern.

13.4.3 Public health risks

13.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

13.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

MOEs for adverse health effects were calculated for adults and children by comparing the highest no-effect dose with exposures estimated from conservative (Tier 1) exposure modelling for various scenarios outlined in Table D.63 and Table D.64 (Table D.66).

Table D.66 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	0.003	0.001

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.63 and Table D.64). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of uncertainty factors derived for this risk characterisation and the use of an epidemiological study in which the mean atmospheric concentration of lime dust associated with adverse effects could not be ascertained, the calculated MOEs indicate that a potential concern for systemic adverse health effects cannot be ruled out for adults and children from repeated exposures following a bulk spill.

However, as noted, calcium hydroxide dissociates into calcium ions and hydroxide ions which are normal physiological components in humans and subject to homeostatic mechanisms to regulate their levels. Therefore, systemic health effects in adults or children from repeated exposures to calcium hydroxide in contaminated water are unlikely and therefore the chemical is of low concern.

Also, the modelled PEC for an accidental bulk transport spill of calcium hydroxide (1169 mg/L) translates into 0.016 M calcium hydroxide concentration, with a pH of about 12. Individuals exposed to such contaminated water will experience eye irritation and therefore

become aware of the contamination. This decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for repeated human exposure would be further reduced.

13.4.4 Conclusions

13.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for skin and respiratory tract irritation and severe eye irritation.

Acute exposure to the chemical via drilling fluids is of potential concern for workers based on the potential for eye irritation.

For repeated exposures of workers to the chemical as delivered to site, the chemical is of low concern for workers.

13.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, the chemical is of low concern. Moreover, due to the nature of the alkalinity expected of water contaminated from an accidental spill, any eye irritation that may occur following bathing will likely mitigate against repeated exposures.

13.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

13.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

13.6 References

- CalEPA (1997) Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels. Draft for Public Review. California Environmental Protection Agency (CalEPA), Office of Environmental Health Hazard Assessment, Air Toxicology and Epidemiology Section, Berkeley, CA.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Dossier on calcium oxide (CAS RN 1305-78-8). European Union. Accessed 11 September 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.
- SCOEL (2008) Recommendation from the European Union Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium hydroxide (Ca(OH)₂) (SCOEL/SUM/137), February 2008.

D14 Calcium oxide

CAS RN	CAS Name
1305-78-8	Calcium oxide

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

14.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. NICNAS notes that the chemical will revert to calcium hydroxide on dissolution in water. Moreover, the CBI concentration is higher than the reported solubility of either calcium oxide or calcium hydroxide in water. Nonetheless, the concentration reported by industry will be used in case solubility enhancers are also used in the liquid formulation.

After incorporation of the chemical into hydraulic fracturing fluid, calcium oxide is present at a CBI concentration.

14.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

In aqueous solutions, calcium oxide dissociates into calcium ions and hydroxide ions. These are normal physiological components in humans, subject to homeostatic mechanisms to regulate their levels. Hydroxide ions are a natural constituent of aqueous solutions arising from the self-ionisation reaction of water. Uptake of hydroxide ions has the potential to increase the pH of the blood. However, blood pH is efficiently regulated by mechanisms such as urinary excretion of bicarbonate and exhalation of carbon dioxide. Calcium is an abundant mineral in the body with a number of important functions including bone mineralisation, blood clotting and neuromuscular function. Ingested calcium oxide (hydroxide) is subject to neutralisation under the acidic conditions of the stomach.

Calcium oxide has low acute oral and dermal toxicity. It is a skin and respiratory irritant and a severe eye irritant. Calcium oxide is not genotoxic or carcinogenic and does not have any developmental effects in animals.

Oral or dermal repeat dose studies are not available for calcium oxide. In an epidemiological study, no significant adverse effects were observed in lime-kiln workers exposed to

1.2 mg/m³ lime dust (calcium oxide and calcium hydroxide). This atmospheric concentration is adopted as an overall No-Observed-Adverse-Effect-Concentration (NOAEC) for calcium hydroxide and is used in this human health risk assessment. However, it should be noted that as this NOAEC represents an atmospheric concentration of the chemical in a workplace, the NOAEC value is likely to be conservative compared to a level that might be determined from laboratory studies.

Apart from non-specific effects such as alkalosis which may occur at high doses, systemic health effects from repeated exposures to calcium oxide are unlikely.

The critical adverse health effects of calcium oxide are skin and respiratory irritation and severe eye irritation.

14.3 Human exposure assessment

14.3.1 Worker exposure

Exposure of workers to calcium oxide is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of particulates during operations. Exposure may also occur from contact with produced water containing residual calcium oxide, which as noted, will be present upon dissolution in water as calcium hydroxide.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.67) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.67 Internal doses resulting from calcium oxide exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic	n.d.	n.d.	n.d.

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
fracturing)			
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage, use, and treatment	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via produced water storage, use and treatment are regarded as negligible (NICNAS 2017a).

14.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of calcium oxide particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to calcium oxide via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of

exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.68) and children (Table D.69).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.68 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.69 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

14.4 Human health risk characterisation

14.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, a conservative NOAEC from a human study (without adverse effects) was used for human health risk assessment. Consequently, an uncertainty factor of only 10 (intra-species variation only) is applied in the MOE calculation, and an MOE of less than 10 is considered a concern.

14.4.2 Occupational health risks

14.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site may result in adverse health effects such as eye irritation, given the extremely damaging nature of the concentrated chemical to the eyes.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemicals (if required) and during manipulation of equipment containing the residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

14.4.2.2 Long-term health risks

Studies on long-term adverse health effects by exposure via oral or dermal routes are not available. The EU Scientific Committee on Occupational Exposure Limits for Calcium Oxide and Calcium Hydroxide reviewed an epidemiological study on the effects of occupational exposure to calcium oxide (SCOEL 2008). In this study, no significant adverse effects were observed in lime-kiln workers exposed to 1.2 mg/m³ lime dust (calcium oxide and calcium hydroxide). This atmospheric concentration is used as an overall NOAEC for calcium hydroxide for the purpose of human health risk assessment.

Assuming 100% inhalation absorption, an average worker body weight of 70 kg, and a respiratory rate of 20 m³ of air (CalEPA 1997), this represents an internal absorbed dose as described in Equation D.3 below.

$$\frac{1.2 \text{ mg/m}^3 \times 20 \text{ m}^3/\text{day} \times 8 \text{ h}}{70 \text{ kg} \times 24 \text{ h}} = 0.114 \text{ mg/kg bw/day} \quad [\text{Equation D.3}]$$

Again, it is emphasised that as this highest no-effect dose is derived from a NOAEC that itself represents a very conservative No-Adverse-Effects Level, the MOE calculations are also very conservative estimates of the safety of the exposure as compared to the no-concern MOE of 10.

The MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the internal absorbed dose with exposures estimated for different occupational activities during drilling (Table D.70).

Table D.70 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.67). ** In the absence of a No-Observed-Adverse-Effect Level (NOAEL), these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during the modelled operations.

Given the low concentration of the chemical in hydraulic fracturing fluids, repeated exposure to the chemical via these fluids is of low concern for workers.

14.4.3 Public health risks

14.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

14.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses, wherein the chemical will effectively be calcium hydroxide.

Based on the critical health effect and NOAEC established in an epidemiological study, MOEs were calculated for adults and children for various exposure scenarios (Table D.71).

Table D.71 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.68 and Table D.69). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

In light of the uncertainty factors derived for this risk characterisation and the use of an epidemiological study in which the dose of the chemical associated with adverse effects could not be ascertained, the MOEs of < 100 for adults and children for the accidental bulk spill scenario suggest that a potential concern for systemic adverse health effects cannot be ruled out for this scenario.

Similarly, for the storage pond leak scenario, MOEs of < 100 for children for groundwater/surface water suggest that a potential concern cannot be ruled out for systemic adverse health effects from repeated exposures.

For the storage pond leak scenario, the MOEs indicate a low concern for adults for all water uses and for children for surface water use.

However, as noted, calcium oxide dissociates into calcium ions and hydroxide ions which are normal physiological components in humans, subject to homeostatic mechanisms to regulate their levels. Therefore, systemic health effects for the public from repeated exposures to calcium oxide (hydroxide) for these exposure scenarios are unlikely and so the chemical is of low concern.

14.4.4 Conclusions

14.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for eye irritation.

Acute exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers during certain operations.

14.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures via environmental contamination, the chemical is regarded as of low concern for the public.

14.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

14.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

14.6 References

- CalEPA (California Environmental Protection Agency) (1997) Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels. Draft for Public Review. Office of Environmental Health Hazard Assessment, Air Toxicology and Epidemiology Section, Berkeley, CA.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on calcium oxide (CAS RN 1305-78-8). European Union. Accessed 11 September 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

SCOEL (2008) Recommendation from the European Union Scientific Committee on Occupational Exposure Limits (SCOEL) for calcium oxide (CaO) and calcium hydroxide (Ca(OH)₂) (SCOEL/SUM/137), Accessed February 2008.

D15 Sodium hydroxide

CAS RN	CAS Name
1310-73-2	Sodium hydroxide

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

15.1 Chemical use and concentration

Sodium hydroxide is used as a component of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is as a pH buffer and cross-linker.

Prior to incorporation into the final drilling and hydraulic fracturing fluids, the chemical, as reported in the coal seam gas industry survey (NICNAS 2017b), is transported, stored and handled as a liquid at a concentration of 1 000 g/L (100% w/v). After incorporation, it is present in drilling fluid at a confidential business information (CBI) concentration, and in the hydraulic fracturing fluid at a CBI concentration.

15.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The information on health hazards is obtained from the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report on sodium hydroxide (OECD 2002). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

When absorbed systemically, the chemical dissociates fully into sodium ions and hydroxide ions. These are normal physiological constituents in humans which are regulated by homeostatic mechanisms. Hydroxide ions are a natural constituent of aqueous solutions arising from the self-ionisation reaction of water. Uptake of hydroxide ions has the potential to increase the pH of the blood. However, blood pH is efficiently regulated by mechanisms such as urinary excretion of bicarbonate and exhalation of carbon dioxide. Excess sodium is excreted predominantly via urine.

Sodium hydroxide has high acute oral and dermal toxicity. Lethality has been reported in animals at oral doses of 240 mg/kg bw. An oral median lethal dose (LD50) of 325 mg/kg bw in rats and a dermal LD50 of 1 350 mg/kg in rabbits were reported for sodium hydroxide.

Sodium hydroxide is corrosive to the skin, eyes and gastrointestinal and respiratory tracts. Based on human data, concentrations of 0.5 - 4.0% are irritating to the skin, while a concentration of 8.0% is corrosive. Sodium hydroxide is not a skin sensitiser.

No animal or human data are available on repeat dose toxicity by oral or dermal routes for sodium hydroxide. In the only available repeat dose inhalation study, a No Observed Adverse Effect Level (NOAEL) was not established. Both *in vitro* and *in vivo* genetic toxicity tests indicated no evidence of a mutagenic activity. Information on reproductive and developmental toxicity and carcinogenicity of sodium hydroxide is not available.

In conclusion, the critical adverse health effect of sodium hydroxide is its corrosive effect. Due to the unavailability of a NOAEL, quantification of risks from repeated exposure is not possible. However, due to dissociation into ions which are subject to homeostatic controls in the human body, systemic effects from repeated exposures to sodium hydroxide are not expected.

15.3 Human exposure assessment

15.3.1 Worker exposure

Exposure of workers to sodium hydroxide is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual sodium hydroxide.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.72) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling and hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.72 Internal doses resulting from chemical exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.060	0.026	0.086
Mixing/blending of hydraulic fracturing chemicals	0.060	0.026	0.086
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Drilling muds transport and storage	Negligible*	Negligible*	Negligible*
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

15.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to chemicals via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water for the different public exposure scenarios. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.73) and children (Table D.74) for drilling exposure scenarios. Separate internal doses were also derived for adults (Table D.75) and children (Table D.76) for hydraulic fracturing scenarios.

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.73 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.39	N/A	33.390
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻³	1.98 x 10 ⁻³
Swimming in contaminated surface water	2.48 x 10 ⁻³	1.98 x 10 ⁻³	4.46 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			33.396
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for surface water (see NICNAS 2017a).

Table D.74 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻³	3.44 x 10 ⁻³
Swimming in contaminated surface water	3.47 x 10 ⁻²	3.68 x 10 ⁻³	3.84 x 10 ⁻²

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			116.907
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**

E_{oral} - Internal dose from oral exposure; *E_{derm}* – Internal dose from dermal exposure; *E_{total}* – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for surface water (see NICNAS 2017a).

Table D.75 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	24.421	N/A	24.421
Bathing in contaminated surface water	Negligible*	1.45 x 10 ⁻³	1.45 x 10 ⁻³
Swimming in contaminated surface water	1.81 x 10 ⁻³	1.45 x 10 ⁻³	3.26 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			24.426
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.76 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	85.475	N/A	85.475
Bathing in contaminated surface water	Negligible*	2.52 x 10 ⁻³	2.52 x 10 ⁻³
Swimming in contaminated surface water	2.54 x 10 ⁻²	2.69 x 10 ⁻³	2.81 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			85.506
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

15.4 Human health risk characterisation

15.4.1 Uncertainty factors

Limited data concerning repeat dose toxicity studies impact on the ability of NICNAS to undertake a more scientifically robust risk assessment. Nonetheless, based on the data that are available, NICNAS has assessed the risks posed by sodium hydroxide in this section.

However, the risk to workers or the general public from long-term exposure to sodium hydroxide could not be quantified using the Margin of Exposure (MOE) approach.

15.4.2 Occupational health risks

15.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as severe damage to skin, eye and respiratory tract. As the chemical is reported to be delivered to sites as a liquid at a concentration of 100% w/v, it is very likely that contact with the chemical will produce these effects.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. Sodium hydroxide, at CBI concentrations in drilling and hydraulic fracturing fluids, may cause skin irritation from acute dermal exposure.

15.4.2.2 Long-term health risks

Risks from long-term repeat dose exposure could not be quantified due to the unavailability of an appropriate repeat dose toxicity study for sodium hydroxide. However, due to dissociation into ions which are subject to homeostatic controls in the human body, systemic effects from repeated exposures to sodium hydroxide are not expected. Other than the potential for local irritant effects, repeated exposure to the chemical is of low concern for workers.

Given the low concentration of sodium hydroxide in hydraulic fracturing fluid, repeated exposure to the chemical via these fluids is of low concern for workers.

15.4.3 Public health risks

15.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

15.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses. There is no quantitative information on the long-term effects of oral and dermal contact with the chemical. However, due to dissociation into ions which are subject to homeostatic controls in the human body, other than the potential for local irritant effects, systemic effects in adults and children from repeated exposures to sodium hydroxide in contaminated water are not expected and the chemical is of low concern for the public from repeated exposures.

The modelled PEC for accidental bulk spill of sodium hydroxide (1 169 mg/L) translates into 0.03 M sodium hydroxide which will have a pH of about 12. Individuals exposed to the contaminated water will experience eye irritation and therefore become aware of the contamination. This decreases the likelihood of a chemical contamination remaining

undetected and so, in this instance, the potential for repeated human exposure would be further reduced.

Other than the potential for local irritant effects, repeated exposure to the chemical via an accidental bulk spill or storage pond leak is likely to be of low concern for adverse health effects for the public.

15.4.4 Conclusions

Based on available data, NICNAS has assessed the risks posed by sodium hydroxide.

15.4.4.1 Occupational health risks

The concentrated form of sodium hydroxide as delivered to operational sites is of potential concern for workers during operations based on the potential for severe damage to skin, eyes and the respiratory tract.

Exposure to the chemical via drilling and hydraulic fracturing fluids is of potential concern for workers based on the potential for skin irritation.

The level of concern from long-term repeated exposure to sodium hydroxide or drilling/hydraulic fracturing fluids containing sodium hydroxide could not be quantified due to the unavailability of an appropriate repeat dose toxicity study with sodium hydroxide. However, other than for local irritant effects, due to the nature of its constituent ions, the chemical is of low concern for workers from repeated exposures.

15.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical in concentrated form and so the chemical in this form is of low concern for the public.

Risk estimates for the public from long-term repeated exposure to sodium hydroxide or drilling/ hydraulic fracturing fluids containing sodium hydroxide could not be quantified due to the unavailability of an appropriate repeat dose toxicity study with sodium hydroxide. However, due to the nature of its constituent ions, the chemical is of low concern for the public for exposures via contaminated water for the modelled exposure scenarios.

Moreover, for the transport spill scenario, due to the high alkalinity expected of water contaminated from a spill of concentrated chemical, the eye irritation that may occur following initial bathing will likely mitigate against repeated exposures.

Overall, other than for local irritant effects, due to the nature of its constituent ions, the chemical is of low concern for the public.

15.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

15.5.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017a), the chemical is currently classified as a workplace hazardous chemical.

For this chemical, risk estimates suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

15.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2002) Screening Information Data Set (SIDS) Initial Assessment Report (SIAR), Sodium hydroxide. Organisation for Economic Co-operation and Development (OECD), Paris. Accessed in April 2013 at <http://www.inchem.org/documents/sids/sids/Naco.pdf>.

D16 Ethanol, 2-amino-

CAS RN	CAS Name
141-43-5	Ethanol, 2-amino-

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

16.1 Chemical use and concentration

The document from here on refers to ethanol, 2-amino (CAS RN 141-43-5) as 'ethanolamine', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 15 g/L (1.5%). After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

16.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The information on health hazards is obtained from the European Commission (EC 1992) and Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers on the chemical (REACH 2013). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Ethanolamine has moderate acute oral and inhalational toxicity and low acute toxicity by the dermal route. The oral and dermal median lethal doses (LD₅₀) in rats are 1 089 mg/kg bw and 2 504 mg/kg bw, respectively, and the median lethal concentration (LC₅₀) is > 1.3 mg/L. It is corrosive to the skin and eyes. Information on its respiratory irritation activity is not available; however, in a repeated dose inhalation study, signs of irritation were reported in the trachea and lungs, indicating that it is respiratory irritant. Ethanolamine is not a skin sensitiser.

The most appropriate oral No Observed Adverse Effect Level (NOAEL) for human health risk assessment purposes is 320 mg/kg bw/day, determined in an oral repeat dose study in rats and based on changes in liver and kidney weights and mortality at higher doses. Repeat dose dermal studies for ethanolamine are not available.

Ethanolamine is not genotoxic or a carcinogen based on available data.

Effects on fertility were observed at a high dose of 1 000 mg/kg bw/day, at which dose maternal toxicity was also observed. No developmental toxicity effects were noted in rats.

Skin, eye and respiratory irritation are the critical adverse health effects for this human health risk assessment. Ethanolamine is also harmful by oral and inhalation routes. The oral NOAEL will be used in this risk assessment for repeated exposure.

16.3 Human exposure assessment

16.3.1 Worker exposure

Exposure of workers to ethanolamine is possible via inadvertent spills and leaks, especially during any required manual handling or emissions of volatilised chemicals and its aerosols during operations. Exposure may also occur from contact with produced water containing residual ethanolamine.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.77) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.77 Internal doses resulting from ethanolamine exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.009	4.90x10 ⁻⁴	9.49x10 ⁻³
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

16.3.2 Public exposure

The public may be exposed to ethanolamine via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised ethanolamine to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to ethanolamine via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.78) and children (Table D.79).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.78 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.033	N/A	0.033
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻⁵	1.98 x 10 ⁻⁵
Swimming in contaminated surface water	2.48 x 10 ⁻⁶	1.98 x 10 ⁻⁵	2.23 x 10 ⁻⁵
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.033
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.79 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.117	N/A	0.117
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻⁵	3.44 x 10 ⁻⁵
Swimming in contaminated surface water	3.47 x 10 ⁻⁵	3.68 x 10 ⁻⁵	7.15 x 10 ⁻⁵
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.117
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

16.4 Human health risk characterisation

16.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

16.4.2 Occupational health risks

16.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical, at concentrations as delivered to the site [15 g/L (1.5%)], will result in adverse health effects such as skin and eye irritation and moderate respiratory tract irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

16.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to ethanolamine is increased liver and kidney weights and mortality at higher doses. The NOAEL established for this effect is 320 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.80).

Table D.80 Margins of Exposure calculated for different occupational activities

Activity	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	33720
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.77).*

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in the hydraulic fracturing fluids repeated exposure to the chemical via these fluids is also of low concern for workers.

16.4.3 Public health risks

16.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

16.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.81).

Table D.81 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	9572	2736
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.78 and Table D.79).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, risk estimates indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

16.4.4 Conclusions

16.4.4.1 Occupational health risks

Ethanolamine as delivered to operational sites is of potential concern for workers during operations based on the potential for skin, eye and respiratory tract irritation.

Acute exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that ethanolamine as delivered to operational sites is of low concern for workers for repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

16.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

16.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

16.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For this chemical, risk estimates suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

16.6 References

- EC (1992) Occupational exposure limits - Criteria document for ethanolamine. Report No. EUR 14240. European Commission (EC), Luxembourg.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier for ethanolamine (CAS RN 141-43-5). European Union. Available at http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8acd6d-e647-0dfc-e044-00144f67d249/DISS-9d8acd6d-e647-0dfc-e044-00144f67d249_DISS-9d8acd6d-e647-0dfc-e044-00144f67d249.html

D17 Bauxite (Al₂O₃.xH₂O), sintered

CAS RN	CAS Name
144588-68-1	Bauxite (Al ₂ O ₃ .xH ₂ O), sintered

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

17.1 Chemical use and concentration

This document from here on refers to bauxite (Al₂O₃.xH₂O), sintered (CAS RN 144588-68-1) as 'sintered bauxite', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a proppant.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a confidential business information (CBI) concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

17.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

There are no toxicity data available for sintered bauxite, however limited data were available for the major constituent, corundum (CAS RN 1302-74-5), which is the alpha crystalline form of aluminium oxide (CAS RN 1344-28-1). As the toxicity of corundum is driven predominantly by aluminium ion, the information available for this polymorph of aluminium oxide is supplemented in this assessment with a wider range of toxicity studies conducted for the gamma form and other minor transitional polymorphs of aluminium oxide that are also grouped under the CAS RN 1344-28-1. In addition, limited toxicity data are available for mullite (CAS RN 1302-93-8), the minor constituent of sintered bauxite. For the purpose of hazard assessment, it is assumed that the effects observed for corundum, aluminium oxide and mullite demonstrate the likely toxicological profile of the chemical.

Information on health hazards was sourced primarily from the following comprehensive reviews: toxicological profiles for metallic aluminium and compounds (ATSDR 2008; WHO 1997, 2012), a human health risk assessment for aluminium, aluminium oxide, and aluminium hydroxide (Krewski et al. 2007) and the Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers on aluminium oxide (REACH 2014a) and mullite (REACH 2014b).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sintered bauxite has low acute oral and inhalation toxicity based on the data available for aluminium oxide (in its general form) and both constituents respectively. Other data available for both constituents indicate the chemical is not irritating to the skin or eye but is a respiratory irritant. Aluminium oxide is not a respiratory sensitiser and aluminium oxide and

mullite are not skin sensitisers; it is therefore likely that sintered bauxite is neither a respiratory sensitiser nor a skin sensitiser.

Repeat dose inhalation studies of aluminium oxide and mullite in animals have reported localised irritant effects and pulmonary changes, including inflammation and influx of mononuclear cells in a mullite study at 10 mg/m³ (2.1 mg/kg bw/day). No systemic effects were reported at any of the doses and no No Observed Adverse Effect Levels (NOAELs) could be derived. In the critical 28-day inhalation study of mullite, there were no adverse systemic effects observed at a dose of 12.6 mg/kg bw/day. An adjustment factor of three is applied to this dose due to the inadequate duration of this study. Consequently, based on the absence of adverse effects observed, for the purposes of quantifying the health risk of sintered bauxite, this highest adjusted tested dose in the critical study (4.2 mg/kg bw/day) is used in this risk assessment.

Sintered bauxite is not genotoxic based on data available for aluminium oxide and mullite, and is not carcinogenic or toxic to fertility based on data available for aluminium oxide.

17.3 Human exposure assessment

17.3.1 Worker exposure

Exposure of workers to sintered bauxite is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations.

Exposure may also occur from contact with produced water containing residual sintered bauxite.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.82) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a). As absorption of sintered bauxite through the skin is considered to be negligible, the internal dose via the dermal route is taken as zero. The absorbed dose via the inhalation route is therefore considered to be the total internal dose.

Table D.82 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

17.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public

exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.83) and children (Table D.84).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

As absorption of sintered bauxite through the skin is considered to be negligible and through inhalation is very low, the internal dose via the dermal route is taken as zero. The absorbed dose via the oral route is therefore considered to be the total internal dose.

Table D.83 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	n.d.	0	0
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	0	0
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	n.d.	0	0
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak –			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water use Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a)

Table D.84 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	n.d.	0	0
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	0	
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	n.d.	0	0
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

17.4 Human health risk characterisation

17.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

17.4.2 Occupational health risks

17.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects, such as respiratory irritation caused by dust inhalation. Given the concentration of the chemical as delivered to operational sites, the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the chemical will be suspended in water, the impact of inhalation of sintered bauxite dusts is therefore not relevant for contact with these fluids, and acute exposure to the chemical via these fluids is therefore of low concern for workers.

17.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at the highest adjusted tested dose of 4.2 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest adjusted no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.85).

Table D.85 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.82). ** In the absence of a NOAEL, these MOEs were calculated based on the highest adjusted dose.

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and a toxicological study that did not identify a dose of the chemical associated with adverse effects, the MOEs indicate a low concern for repeated exposures under the modelled scenarios.

17.4.3 Public health risks

17.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

17.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at the highest adjusted tested dose of 4.2 mg/kg bw/day. Based on this highest adjusted no-effect dose, MOEs were calculated for adults and children for various exposure scenarios (Table D.86).

Table D.86 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)**(ADULT)	Margin of Exposure (MOE)**(CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.83 and Table D.84). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects, and an MOE < 100 derived for repeated

exposures of children to contaminated groundwater/surface water from a leaking storage pond, a potential concern cannot be ruled out for systemic adverse health effects. However, the MOEs > 100 for adults and children for the other exposure scenarios indicate a low concern for the public from repeated exposures to contaminated water for these scenarios.

17.4.4 Conclusions

17.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for respiratory irritation.

Acute exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

17.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from a bulk spill during transport or a leaking storage pond (surface water use), calculated MOEs indicate a low concern for adults or children. For the leaking storage pond scenario (groundwater/surface water use), based on the MOE a potential concern cannot be ruled out for children from repeated exposures to contaminated water.

17.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

17.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For this chemical, risk estimates suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on the legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

17.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions as to the level of concern for the public from exposure to sintered bauxite in contaminated water for all exposure scenarios involving a leaking storage pond. Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

17.5.2.1 Storage of flowback and / or produced water

For chemicals with potential concerns from contamination of shallow groundwater from a leaking storage pond, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits / ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

17.6 References

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D18 Quartz (SiO₂), Cristobalite (SiO₂), Tridymite (SiO₂), and Diatomite, calcined

CAS RNs.	CAS Names
14808-60-7	Quartz (SiO ₂)
14464-46-1	Cristobalite (SiO ₂)
15468-32-3	Tridymite (SiO ₂)
91053-39-3	Diatomite, calcined

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

18.1 Chemical use and concentration

All three forms of crystalline silica and the diatomite calcined silica are used as components of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. Their functions within these fluids are described as proppants and cross-linkers.

Prior to incorporation into the final drilling or hydraulic fracturing fluids, the chemicals as reported in the coal seam gas industry survey (NICNAS 2017b) are transported, stored and handled as solids. Their concentrations in products prior to incorporation into drilling and hydraulic fracturing fluids and after dilution (final concentration in the fluids) are given in Table D.87, and they range from 0.1 to 0.5% in drilling fluid products and generally the pure chemical for hydraulic fracturing products. These chemicals are then diluted further when used in drilling or hydraulic fracturing liquids, being in the range of 0.003 - 12%. Where the concentrations of the chemicals in the products were not provided by the industry, a default value of 1 000 g/Kg prior to incorporation into fluids is assumed.

Table D.87 Physical state and concentrations of the chemicals in products and drilling and hydraulic fracturing fluids

Chemical name (CAS RN)	Physical state of the product	Concentration in product (g/L or g/kg)		Concentration in fluids (g/L)	
		Drilling	Hydraulic fracturing	Drilling	Hydraulic fracturing
Cristobalite (14464-46-1)	Solid	10	CBI	0.497	CBI
Quartz (14808-60-7)	Solid	50	2650	7.77	120
Tridymite (15468-32-3)	Solid	10	Not used	0.432	Not used
Calcined diatomite (91053-39-3)	Not known	Not used	1 000	Not used	0.0344

CBI – confidential business information

18.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this group of chemicals (NICNAS 2017c).

Information on health hazards is obtained from the following comprehensive reviews of crystalline silica – the International Agency for Research on Cancer (IARC) Monograph (IARC 1997, 2012), World Health Organisation (WHO 2000), US Environmental Protection Agency (US EPA1996), and Health Canada (Health Canada 2011).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Data on the acute oral, dermal and inhalation effects of quartz, cristobalite, tridymite or calcined diatomaceous earth in humans or experimental animals are not available. The substances are not skin or eye irritants, although acute inhalation of dust may cause discomfort and stress as well as signs of local irritation to nasal, bronchiolar and ocular mucous membranes. The skin sensitisation potential of these chemicals is not known, although based on their structures and physico-chemical properties, the three forms of crystalline silica and the calcined diatomaceous earth are not expected to cause skin sensitisation.

Data on oral and dermal repeat dose toxicity of silica are not available. In experimental animals, repeated inhalation and intratracheal exposure to crystalline silica induced inflammation, elevated levels of granulocytes and cytotoxicity of lung tissue. In humans the main critical non-neoplastic effects of crystalline silica are silicosis, silicotuberculosis, enlargement of the heart (cor pulmonale), interference with the body's immune system and damage to the kidneys. The most frequently reported autoimmune diseases in crystalline silica exposed workers are scleroderma, rheumatoid arthritis, polyarthritis, mixed connective tissue disease, systemic lupus erythematosus, autoimmune haemolytic anaemia, and dermatopolymyositis. A Lowest-Observed-Adverse-Effect-Concentration (LOAEC) of 0.05 mg/m³ for crystalline silica was established in humans based on the incidence of silicosis in mine workers exposed to the chemical.

The results of genotoxicity studies on crystalline silica conflict, so a direct genotoxic effect for crystalline silica has not been confirmed or ruled out. Studies on the effect of silica on reproductive and developmental parameters are not available.

There are extensive data on the carcinogenic effects of crystalline silica; both from animal and human epidemiological studies investigating the link between crystalline silica exposure and cancer. The IARC identified more than 50 epidemiological studies on lung cancer from occupational exposure to dust containing respirable crystalline silica. Based on the evaluation of the epidemiological data, it is concluded that inhalation exposure to crystalline silica can result in lung cancer. This is also supported by animal studies in which inhalation and intratracheal exposure to crystalline silica resulted in lung tumours.

There is also evidence that the incidence of lung cancer increases with increasing cumulative exposure to respirable crystalline silica dust and that the relative lung cancer risk is increased for persons with silicosis.

Overall, the most sensitive effects from exposure to crystalline silica and calcined diatomite are silicosis and lung cancer via the inhalation route. For inhalation repeat dose toxicity, a LOAEC of 0.05 mg/m³ was established based on the incidence of silicosis in epidemiological studies.

In the absence of an appropriate No-Observed-Adverse-Effect Level (NOAEL), the available LOAEC (0.05 mg/m³) is used in this human health risk assessment.

18.3 Human exposure assessment

18.3.1 Worker exposure

Exposure of workers to drilling and hydraulic fracturing chemicals is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of particulates during operations. Exposure may also occur from contact with produced water containing residual fracturing chemicals.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities mixing / blending plus cleaning and maintenance activities.

The total human (internal) doses for each form of crystalline silica and calcined diatomaceous earth (Table D.88 and Table D.89) were estimated using exposure modelling and inhalation absorption rates determined from the hazard characterisation. Further details on the derivation of exposure estimates are available in a separate exposure assessment report for coal seam gas chemicals (NICNAS 2017a). As absorption of all forms of silica through the skin is considered to be negligible, and the internal dose via dermal route is taken as zero, the absorbed dose through the inhalation route is considered as the total internal dose.

Table D.88 Internal doses resulting from inhalation exposure to the four forms of silica associated with drilling occupational activities

Occupational activity	Cristobalite (mg/kg bw/day)	Quartz (mg/kg bw/day)	Tridymite (mg/kg bw/day)	Calcined diatomite (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*	Not used
Mixing/blending of drilling chemicals	0.0003	0.001	2.6x10 ⁻⁴	"
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*	"
Cleaning and maintenance (drilling)	5.2x10 ⁻⁵	8.14x10 ⁻⁴	4.53x10 ⁻⁵	"
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	3.14x10 ⁻⁴	0.002	3.07x10 ⁻⁴	"

Occupational activity	Cristobalite (mg/kg bw/day)	Quartz (mg/kg bw/day)	Tridymite (mg/kg bw/day)	Calcined diatomite (mg/kg bw/day)
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*	"

* In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

Table D.89 Internal doses resulting from inhalation exposure to the four forms of silica associated with hydraulic fracturing occupational activities

Occupational activity	Cristobalite (mg/kg bw/day)	Quartz (mg/kg bw/day)	Tridymite (mg/kg bw/day)	Calcined diatomite (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Not used	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	0.070	"	0.026
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	"	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	0.013	"	3.60x10 ⁻⁶
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.	0.080	"	0.026
Produced water transport and storage	Negligible*	Negligible*	"	Negligible*

n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

18.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)

- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of silica particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the silica via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling can be used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total human (internal) dose can then be estimated using these PECs and oral and dermal absorption rates determined from the hazard characterisation. However, since the oral and dermal absorption of all forms of silica are considered to be nil, exposure to silica through these two routes was not considered further.

Public exposure to silica by all three routes was therefore considered to be negligible.

18.4 Human health risk characterisation

18.4.1 Uncertainty factors

For the risk assessment using a Margin of Exposure (MOE) approach, an uncertainty factor is applied if, due to the lack of an adequate NOAEL, a Low-Observed-Adverse-Effect-Level (LOAEL) is used in the MOE calculation. This uncertainty factor assumes that the chosen LOAEL is reasonably close to the projected NOAEL in a study, and that the use of this uncertainty factor will drop the LOAEL into the range of the expected NOAEL (Dourson et al. 1996). Published studies in which the ratios of LOAELs to NOAELs were compared for a range of different chemicals and different study durations (sub-acute, sub-chronic and chronic) indicate that the LOAEL rarely exceeds the NOAEL by more than about 5-6 fold and is typically closer to threefold. ECETOC (1995) recommended a factor of three for LOAEL to NOAEL extrapolation in the majority of cases, based on the approximate mean of the available experimental data in the literature. Since a LOAEL is being used in this risk assessment, an uncertainty factor of three will be applied for the MOE calculations.

An additional uncertainty factor of 10 was applied in the MOE calculation, since the LOAEC for the risk assessment was taken from a human study (intraspecies variation only; see Section 18.2).

Taken together, an MOE of less than 30 is considered a concern.

18.4.2 Occupational health risks

18.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site is unlikely to result in health effects. Therefore, the chemical in this form is of low concern for workers.

18.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures to crystalline silica in humans are silicosis, silicotuberculosis and lung cancer. The LOAEC established for this effect in human epidemiological studies is 0.05 mg/m^3 . Assuming 100% inhalation absorption, an average worker body weight of 70 kg, and a respiratory rate of 20 m^3 of air (CalEPA 1997), this represents an absorbed dose of:

$$0.05 \text{ mg/m}^3 \times 20 \text{ m}^3/\text{day} \times 8 \text{ h} = \frac{0.0048 \text{ mg/kg bw/day}}{70 \text{ kg} \times 24 \text{ h}} \quad [\text{Equation D.4}]$$

The MOE for adverse health effects from repeated occupational exposures is calculated by comparing the LOAEL for this effect with exposures estimated for different occupational activities during drilling (Table D.90) and hydraulic fracturing (Table D.91).

Table D.90 Margins of Exposure calculated for different occupational activities during drilling

Activity*	Margin of Exposure (MOE)			
	<i>Cristobalite</i>	<i>Quartz</i>	<i>Tridymite</i>	<i>Calcined</i>
Mixing/blending of drilling chemicals	18	4	18	Not used
Cleaning and maintenance (drilling)	92	6	106	"
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	15	3	16	"

* MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.88).

Table D.91 Margins of Exposure calculated for different occupational activities during hydraulic fracturing

Activity*	Margin of Exposure (MOE)			
	<i>Cristobalite</i>	<i>Quartz</i>	<i>Tridymite</i>	<i>Calcined</i>
Mixing/blending of hydraulic fracturing chemicals	n.d.	0.070	Not used	0.180
Cleaning and maintenance (hydraulic fracturing)	n.d.	0.380	"	1333
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.	0.060	"	0.180

n.d. – not disclosed. * MOEs for transport/storage, injection and handling of flowback/ produced water not calculated due to negligible human exposures (Table D.89).

For drilling, based on uncertainty factors derived for this risk characterisation, the MOEs indicate that all three forms of crystalline silica and calcined diatomite silica, as delivered to operational sites, are of low concern for workers from repeated exposures during certain operations. For hydraulic fracturing processes, the MOEs indicate that quartz, tridymite and calcined diatomite silica are of potential concern while cristabolite is of low concern for workers. There is sufficient evidence from numerous epidemiological studies to indicate that silicosis, the main effect in humans after occupational inhalation of respirable silica dust, is associated with the development of lung cancer.

18.4.3 Public health risks

Due to negligible absorption of the crystalline silicas by the oral and dermal routes, the chemicals are of low concern for the public.

18.4.4 Conclusions

18.4.4.1 Occupational health risks

Given the lack of adverse health effects from acute exposures, the four forms of crystalline silica in concentrated form are of low concern for workers during operations.

Calculated MOEs indicate that the four forms of silica as delivered to operational sites are of potential concern for workers from repeated aerosol exposures during drilling operations with the potential for silicosis and lung cancer. For hydraulic fracturing operations, quartz, tridymite and calcined diatomite silica are similarly of potential concern for workers. Cristabolite is of low concern for workers.

18.4.4.2 Public health risks

The public is unlikely to come into contact with the chemicals in concentrated form and so in this form the chemicals are of low concern for the public.

Repeated exposure of the public via contaminated water is not possible as the absorption of crystalline silica through oral and dermal routes is negligible. Silica is therefore of low concern for adults and children based on the modelled exposure scenarios.

18.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

18.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), crystalline silicas in the form of quartz and cristabolite require classification as workplace hazardous chemicals. Accordingly, the classification of the chemicals has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as these chemicals, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemicals depend on the physical form and the manner in which the chemicals are used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

18.6 References

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- WHO (2000) Concise International Chemical Assessment Document 24 - Crystalline Silica, Quartz. Produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals, World Health Organisation (WHO) Geneva.

D19 Boric acid (H₃BO₃), compound with 2-aminoethanol

CAS RN	CAS Name
26038-87-9	Boric acid (H ₃ BO ₃), compound with 2-aminoethanol

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

19.1 Chemical use and concentration

The document from here on refers to Boric acid (H₃BO₃), compound with 2-aminoethanol (CAS RN 26038-87-9) as 'MEA polyborate', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 600 g/L (60%). After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

19.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). Information on health hazards was obtained predominantly from the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

MEA polyborate has low acute oral toxicity. Information on acute inhalation toxicity is not available. It is not a skin or eye irritant. Results from acute dermal and sensitisation studies using a closely related compound (boric acid reaction products with monoethanolamine and triethanolamine) indicate that MEA polyborate is likely to have low acute dermal toxicity and is not likely to be a skin sensitiser.

No repeat dose toxicity studies were available for MEA polyborate. An appropriate No-Observed-Adverse-Effect Level (NOAEL) for repeat dose toxicity by any exposure route could not be established in animal studies conducted with closely related compounds such as 'boric acid reaction products with monoethanolamine and triethanolamine'.

However, since MEA polyborate is likely to hydrolyse into boric acid and monoethanolamine under physiological conditions, critical effects related to these two chemicals are relevant to this risk assessment.

Repeated exposures to boric acid induce effects on fertility, development and the blood system. The oral No-Observed-Adverse-Effect Level (NOAEL) for effects on fertility and the blood system (haemotoxicity) was 17.5 mg boron/kg bw/day. This NOAEL was the equivalent of 100 mg boric acid/kg bw/day and 200 mg/kg bw/day MEA polyborate (considering 1:1 ratio of boric acid and monoethanolamine in the MEA polyborate complex).

The NOAEL for developmental toxicity (foetal development) was 9.6 mg boron/kg bw/day. This NOAEL was the equivalent of 55 mg boric acid/kg bw/day and 110 mg/kg bw/day MEA polyborate (considering 1:1 ratio of boric acid and monoethanolamine in the MEA polyborate complex).

Ethanolamine has low repeat dose oral and inhalation toxicity. Repeated oral exposure to ethanolamine resulted in increase in liver and kidney weights with a NOAEL of 320 mg/kg bw/day. Ethanolamine was shown not to be a skin sensitiser, genotoxin or carcinogen.

MEA polyborate was not genotoxic. Carcinogenicity data are not available for MEA polyborate or its components ethanolamine and boric acid. Boric acid was shown not to be a skin sensitiser, genotoxin or carcinogen.

NOAELs from studies with boric acid are used for this risk assessment of MEA polyborate.

19.3 Human exposure assessment

19.3.1 Worker exposure

Exposure of workers to MEA polyborate is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual MEA polyborate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.92) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.92 Internal doses resulting from MEA polyborate exposures associated with hydraulic fracturing occupational activities

Occupational activity	Ederm (mg/kg bw/day)	Einh (mg/kg bw/day)	Etotal (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.289	0.318	0.607

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

19.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised MEA polyborate to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to MEA polyborate via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.93) and children (Table D.94).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.93 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	Eoral (mg/kg bw/day)	Ederm (mg/kg bw/day)	Ettotal (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	16.094	N/A	16.094
Bathing in contaminated surface water	Negligible*	9.55×10^{-3}	9.55×10^{-3}
Swimming in contaminated surface water	1.19×10^{-3}	9.55×10^{-3}	1.07×10^{-2}
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			16.114
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.94 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	56.329	N/A	56.329
Bathing in contaminated surface water	Negligible*	1.66 x 10 ⁻²	1.66 x 10 ⁻²
Swimming in contaminated surface water	1.67 x 10 ⁻²	1.77 x 10 ⁻²	3.44 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			56.380
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

19.4

19.5 Human health risk characterisation

19.5.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

19.5.2 Occupational health risks

19.5.2.1 Acute health risks

Health effects information indicates that acute exposure to pure MEA polyborate is unlikely to result in adverse health effects. Therefore, the chemical as delivered to the site is of low concern for acute adverse health effects for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

19.5.2.2 Long-term health risks

Long-term repeat dose studies for MEA polyborate by any route are not available. Since MEA-polyborate is likely to hydrolyse into boric acid and ethanolamine under physiological conditions, critical effects related to these two chemicals are considered relevant.

Ethanolamine does not have significant adverse effects in animals following repeated oral exposure. However, boric acid shows adverse effects on the fertility and development of experimental animals and is also haemotoxic. The most sensitive endpoint for boric acid is its effects on development with a No-Observed-Adverse-Effect Level (NOAEL) of 55 mg/kg bw/day, equivalent to a NOAEL of 110 mg/kg bw/day for MEA-polyborate. As this health effect identified from prenatal developmental toxicity testing in animals is not relevant for non-pregnant members of the public, MOEs were also calculated for workers for various exposure scenarios based on haemotoxicity. The NOAEL for this effect was 100 mg/kg bw/day for boric acid, equivalent to 200 mg/kg bw/day for MEA polyborate.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAELs with the exposures estimated for different occupational activities (Table D.95). For the purposes of this risk assessment, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity/male fertility effect of boric acid.

Table D.95 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	180**/330***
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. *MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.92). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/male fertility.

Based on uncertainty factors derived for this risk characterisation, MOEs indicate that the chemical is of low concern for adverse health effects for workers from repeated exposures during certain operations.

19.5.3 Public health risks

19.5.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

19.5.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects (developmental toxicity, haemotoxicity and male fertility) and NOAELs established for these different effects, MOEs were calculated for adults and children for various exposure scenarios (Table D.96).

Table D.96 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	7** 12***	N/A** 4***
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking, bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak –	n.d.	n.d.

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
surface water use Drinking, bathing and swimming in contaminated surface water		

*N/A The consideration of developmental toxicity (foetal development) is not relevant for children and so MOEs for this health effect were not calculated for children; n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.93 and Table D.94). ** MOE based on developmental toxicity (foetal development). *** MOE based on haemotoxicity/male fertility.*

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures based on the modelled exposure scenario of a bulk spill of chemical for use in hydraulic fracturing fluid from a transport accident.

For this bulk spill scenario, MOEs were calculated for both developmental toxicity (foetal development) and haemotoxicity/male fertility. For adults, the MOEs are suggestive of a potential concern for both developmental toxicity and haemotoxicity. For children, developmental toxicity (foetal development) is not relevant and therefore MOEs for this effect were not calculated. However, the calculated MOE based on haemotoxicity is suggestive of a potential concern for this effect in children.

In contrast, the chemical is of low concern for either adults or children based on the modelled exposure scenario of a long-term subsurface leak from a produced water storage pond.

It should be noted that as much as some MOEs suggest potential risks of adverse health effects for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

19.5.4 Conclusions

19.5.4.1 Occupational health risks

Given the lack of acute adverse health effects, MEA polyborate as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids or via produced water is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

19.5.4.2 Public health risks

The public is unlikely to come into contact with the chemical in concentrated form and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative (Tier 1) exposure modelling suggested a potential concern for adults and children based on certain modelled exposure scenarios such as drinking, bathing and swimming in contaminated surface water following an accidental bulk spill. These effects will arise from boric acid, expected to be produced either by hydrolysis of MEA polyborate in environmental waters or by hydrolysis in the body.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

19.6 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

19.6.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

19.6.2 *Control measures available to minimise risks to the public*

19.6.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

19.7 References

NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial

Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on MEA borate (CAS RN 26038-87-9). European Union. Accessed 11 September 2013 <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D20 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer (PolyDADMAC)

CAS RN	CAS Name
26062-79-3	2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer (PolyDADMAC)

20.1 Chemical use and concentration

The document from here on refers to 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer (CAS RN 26062-79-3) as 'polyDADMAC', one of the synonyms of the chemical.

The homopolymer, polyDADMAC, is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a clay control agent.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 651 g/L (65%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 1.3 g/L (0.13%).

20.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017a). Very limited toxicological data are available for polyDADMAC. Information on health hazards was obtained predominantly from studies by John and Trollip (2009), Nozaic et al. (2001) and Palmer (1991). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Being a high molecular weight polymer (molecular weight ~2-3 million), absorption and consequent acute or repeated dose toxicity by oral and dermal routes are not expected. It may have eye, skin and respiratory irritation effects by virtue of the quaternary ammonium moiety in the molecule. However, no experimental data are available. No critical adverse health effects are known for polyDADMAC. Multigenerational reproductive studies with polyDADMAC did not show any effects on fertility or developmental parameters. In a developmental study, doses of up to 600 mg/kg bw/day polyDADMAC did not have any adverse effect on fetuses in Sprague Dawley rats. In the absence of an appropriate No-Observed-Adverse-Effect Level (NOAEL), the highest tested concentration (600 mg/kg bw/day) will be used for human health risk assessment.

20.3 Human exposure assessment

20.3.1 Worker exposure

Exposure of workers to polyDADMAC is possible via inadvertent spills and leaks, especially during any required manual handling or from emissions of aerosols during operations.

Exposure may also occur from contact with produced water containing residual polyDADMAC.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of polyDADMAC as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

Dermal absorption of polyDADMAC is negligible. The total internal human dose (Table D.97) was therefore estimated using exposure modelling and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.97 Internal doses resulting from polyDADMAC exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0	0.017	0.017
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0	1.36x10 ⁻⁴	1.36x10 ⁻⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	0	0.017	0.017
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* – Internal dose from inhalation exposure; *E_{total}* – Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

20.3.2 Public exposure

The public may be exposed to polyDADMAC via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised polyDADMAC to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to polyDADMAC via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling can be used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total human (internal) dose can then be estimated using these PECs and oral and dermal absorption rates determined from the hazard characterisation. However, since the oral and dermal absorption of polyDADMAC are considered to be nil, public exposure to polyDADMAC through these two routes was not considered further.

In summary, public exposure to polyDADMAC by all three routes was considered to be negligible, and therefore risk to the public from the use of polyDADMAC was not evaluated further.

20.4 Human health risk characterisation

20.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

20.4.2 Occupational health risks

20.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical, as delivered to the site (651 g/L, 65%), may result in adverse health effects such as skin, eye and respiratory tract irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

PolyDADMAC is a component of hydraulic fracturing fluid. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (1.3 g/L, 0.13%), acute exposure to the chemical via these fluids is of low concern for workers.

20.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 600 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.98).

Table D.98 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	3.52 x 10 ⁴
Cleaning and maintenance (hydraulic fracturing)	4.41 x 10 ⁶
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	3.49 x 10 ⁴

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.97). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for adverse health effects for workers from repeated exposures during certain operations.

20.4.3 Public health risks

20.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Given the oral and dermal absorption of polyDADMAC is considered to be nil, and public exposures via ambient air are likely to be low, polyDADMAC is of low concern for the public.

20.4.4 Conclusions

20.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites may pose a potential concern for workers during operations based on the potential for skin, eye and respiratory tract irritation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical, as delivered to operational sites, is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

20.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

Given the oral and dermal absorption of polyDADMAC are considered to be nil, and exposure by air to be low, the use of polyDADMAC in coal seam gas operations is of low concern for the public.

20.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

20.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently not classified and is not recommended for classification as a workplace hazardous chemical.

However, for this chemical, risk estimates suggest a potential concern for workers.

Persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

20.6 References

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<http://www.wrc.org.za/Knowledge%20Hub%20Documents/Research%20Reports/1600-1-09.pdf>
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- Palmer K (1991) Poly (dimethyl diallyl ammonium chloride) (PDADMAC) -Oral (Gavage) Rat Teratology Study. Toxicol Laboratories, Ltd., Ledbury, UK.

D21 3(2H)-Isothiazolone, 5-chloro-2methyl-

CAS RN	CAS Name
26172-55-4	3(2H)-Isothiazolone, 5-chloro-2methyl-

21.1 Chemical use and concentration

The document from here on refers to 3(2H)-Isothiazolone, 5-chloro-2methyl- (CAS RN 26172-55-4) as 'methylchloroisothiazolinone', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its functions within these fluids are as a crosslinker, pH buffer, breaker, surfactant, bactericide, or clay stabiliser.

No identity or concentration data were provided for methylchloroisothiazolinone in submissions to an industry survey of chemicals used for coal seam gas extraction in Australia (NICNAS 2017b). Several hydraulic fracturing fluid compositions disclosed in the web-based FracFocus database (GWPC and IOGCC 2014), a national hydraulic fracturing chemical registry in the United States, showed that methylchloroisothiazolinone has a maximum concentration of 10% in additives prior to formulation of the hydraulic fracturing fluid. Thus, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled as a liquid at a concentration of 10%.

After incorporation into the final hydraulic fracturing fluid, it is present at a concentration of 0.0037 g/L (0.00037%) as indicated in the industry survey (NICNAS 2017b).

21.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical. The chemical was assessed as part of a group assessment of isothiazolinones, which also included the chemical methylisothiazolone (CAS RN 2682-20-4) (NICNAS 2017c).

Information on health hazards was obtained predominantly from the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP 2003, 2004) and the Scientific Committee on Consumer Safety (SCCS 2009).

Methylchloroisothiazolinone has high acute oral, dermal, and inhalation toxicity, and is corrosive to the skin, based on read-across data available for the 3:1 mixture of methylchloroisothiazolinone and methylisothiazolone. Methylchloroisothiazolinone is also a strong skin sensitiser.

The critical health effect of the chemical is skin sensitisation. In high concentrations, the chemicals are also corrosive.

Based on the absence of systemic adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk the highest dose tested in the critical study (17.2 mg/kg bw/day) is used in this risk assessment.

Methylchloroisothiazolinone, based on read-across data available for a 3:1 mixture of methylchloroisothiazolinone and methylisothiazolone, is not genotoxic, carcinogenic, or a reproductive toxicant.

21.3 Human exposure assessment

21.3.1 Worker exposure

Exposure of workers to methylchloroisothiazolinone is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual methylchloroisothiazolinone.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.99) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.99 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.060	0.080	0.140
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	4.44 x 10 ⁻⁵	1.18 x 10 ⁻⁵	5.62 x 10 ⁻⁵
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.140
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

21.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.100) and children (Table D.101).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.100 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻³	1.98 x 10 ⁻³
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻³	2.23 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.343
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.002	N/A	0.002
Bathing in contaminated groundwater	Negligible*	8.37 x 10 ⁻⁷	8.37 x 10 ⁻⁷
Drinking contaminated surface water	2.74 x 10 ⁻⁷	N/A	2.74 x 10 ⁻⁷
Bathing in contaminated surface water	Negligible*	1.52 x 10 ⁻¹⁰	1.52 x 10 ⁻¹⁰
Swimming in contaminated surface water	2.03 x 10 ⁻¹¹	1.63 x 10 ⁻¹⁰	1.83 x 10 ⁻¹⁰
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.002
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.74 x 10 ⁻⁷

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.101 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻³	3.44 x 10 ⁻³
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻³	7.15 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.697
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.005	N/A	0.005
Bathing in contaminated groundwater	Negligible*	1.55 x 10 ⁻⁶	1.55 x 10 ⁻⁶
Drinking contaminated surface water	9.58 x 10 ⁻⁷	N/A	9.58 x 10 ⁻⁷
Bathing in contaminated surface water	Negligible*	2.82 x 10 ⁻¹⁰	2.82 x 10 ⁻¹⁰
Swimming in contaminated surface water	2.84 x 10 ⁻¹⁰	3.02 x 10 ⁻¹⁰	5.86 x 10 ⁻¹⁰
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.005
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			9.59 x 10 ⁻⁷

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

21.4 Human health risk characterisation

21.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

21.4.2 Occupational health risks

21.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical or its solution will result in adverse health effects such as acute dermal and inhalation toxicity, skin and eye irritation, and skin sensitisation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed. Given the assumed concentration of the chemical being 10% as delivered to site, contact with the chemical at this concentration is likely to result in acute health effects and so is of potential concern for workers.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids of 0.0037 g/L (0.00037%), exposure to the chemical via these fluids is of low concern for workers.

21.4.2.2 Long-term health risks

From the hazard characterisation, there are no systemic adverse effects observed from repeated exposures to the chemical at any dose tested, up to 17.2 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.102).

Table D.102 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	123
Cleaning and maintenance (hydraulic fracturing)	3.06 x 10 ⁵
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	122

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.97). ** In the absence of a No-Observed-Adverse-Effect Level (NOAEL), these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

21.4.3 Public health risks

21.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

21.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and No Observed Adverse Effect Level (NOAEL) established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.103).

Table D.103 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	5	2
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	1.14×10^4	3259
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	6.27×10^7	1.79×10^7

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.100 and Table D.101). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, and toxicological studies that did not identify a dose of the chemical associated with adverse effects, based on the MOEs < 100 derived for repeated public exposures in the event of an accidental transport spill a potential concern cannot be ruled out for adults and children. However, MOEs > 100 for the storage pond leak scenario indicate that repeated exposure via environmental contamination from this scenario is of low concern for the public.

21.4.4 Conclusions

21.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute dermal and inhalation toxicity, skin and eye irritation, and skin sensitisation.

Calculated MOEs indicate that the chemical is of low concern for chronic adverse health effects for workers from repeated exposures during operations.

21.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk spill, based on the MOEs a potential concern cannot be ruled out for adults and children. Calculated MOEs indicate that the chemical is of low concern for adults and children from repeated exposures via environmental contamination from a leaking storage pond.

21.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

21.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

21.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for systemic adverse health effects for adults and children from repeated exposure to the chemical from water contamination resulting from some of the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

21.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

21.6 References

- GWPC and IOGCC 2014, *FracFocus 2.0*, Ground Water Protection Council (GWPC) and Interstate Oil and Gas Compact Commission (IOGCC), US. Available at <<http://fracfocus.org/http://fracfocus.org/>>.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- SCCNFP (2003) Opinion concerning Methylisothiazolinone Colipa n° P94. Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers. SCCNFP/0625/02, final.
- SCCNFP (2004) Opinion concerning Methylisothiazolinone Colipa n° P94. Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, SCCNFP/0805/04.
- SCCS (2009) Opinion on the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazolin-3(2H)-one Colipa Colipa n° P56. Scientific Committee on Consumer Safety, SCCS/1238/09.

D22 1,2-Benzisothiazol-3(2H)-one

CAS RN	CAS Name
2634-33-5	1,2-Benzisothiazol-3(2H)-one

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

22.1 Chemical use and concentration

The document from here on refers to 1,2-Benzisothiazol-3(2H)-one (CAS RN 2634-33-5) as 'benzisothiazolinone', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled at a CBI concentration with an unspecified concentration unit and physical state. The product is assumed to be a liquid at this CBI concentration.

After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

22.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazard was obtained predominantly from the Scientific Committee on Consumer Safety (SCCS 2012) and the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP 2004).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Benzisothiazolinone demonstrates acute oral toxicity effects, irritation of the skin, corrosive effects in the eyes, and skin sensitisation.

Repeated oral exposure causes increased incidence of histopathological lesions on the non-glandular stomach which are attributed to the local irritant effects of the chemical. The most appropriate No Observed Adverse Effect Level (NOAEL) for risk assessment purposes is 25.26 mg/kg bw/day, based on a decrease in bodyweight gain and salivation at the Lowest Observed Adverse Effect Level (LOAEL) of 63.15 mg/kg bw/day.

The chemical is not genotoxic. Benzisothiazolinone shows no fertility effects.

22.3 Human exposure assessment

22.3.1 Worker exposure

Exposure of workers to benzisothiazolinone is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during

operations. Exposure may also occur from contact with produced water containing residual benzisothiazolinone.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.104) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.104 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

22.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to chemicals via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water, and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.105) and children (Table D.106).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.105 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.106 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

22.4 Human health risk characterisation

22.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

22.4.2 Occupational health risks

22.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical will result in acute adverse health effects, such as skin and eye irritation (at concentrations $\geq 5\%$), and skin sensitisation (at concentrations $\geq 0.05\%$). However, given the concentration of the chemical

as delivered to operational sites, the chemical in this form is of low concern for workers with regards to skin and eye irritation, but is a potential concern with regards to skin sensitisation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

22.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is salivation and decreased bodyweight gain. The NOAEL established for this effect is 25.26 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.107).

Table D.107 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.104).*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

22.4.3 Public health risks

22.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

22.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.108).

Table D.108 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.105 and Table D.106).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

22.4.4 Conclusions

22.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for skin sensitisation.

Exposure to the chemical via hydraulic fracturing fluids or via produced water is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

22.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

22.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

22.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For this chemical, risk estimates suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

22.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- SCCNFP (2004) Opinion concerning Benzisothiazolinone Colipa n° P96. Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, SCCNFP/0811/04.
- SCCS (2012) Opinion on Benzisothiazolinone Colipa n° P96. Scientific Committee on Consumer Safety, SCCS/1482/12.

D23 3(2H)-Isothiazolone, 2-methyl-

CAS RN	CAS Name
2682-20-4	3(2H)-Isothiazolone, 2-methyl-

23.1 Chemical use and concentration

The document from here on refers to 3(2H)-Isothiazolone, 2-methyl- (CAS RN 2682-20-4) as 'methylisothiazolone', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its functions within these fluids are as a crosslinker, pH buffer, breaker, surfactant, bactericide, or clay stabiliser.

No identity or concentration data were provided for methylisothiazolone in submissions to an industry survey of chemicals used for coal seam gas extraction in Australia (NICNAS 2017b). Several hydraulic fracturing fluid compositions disclosed in the web-based FracFocus database (GWPC and IOGCC 2014), a national hydraulic fracturing chemical registry in the United States, showed that methylisothiazolone has a maximum concentration of 5% in additives prior to formulation of the hydraulic fracturing fluid. Thus, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled as a liquid at a concentration of 5%.

After incorporation into the final hydraulic fracturing fluid, it is present at a concentration of 0.0011 g/L (0.00011%) as indicated in the industry survey (NICNAS 2017b).

23.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical. The chemical was assessed as part of a group assessment of isothiazolinones, which also included the chemical methylchloroisothiazolinone (CAS RN 26172-55-4) (NICNAS 2017c).

Information on health hazard was obtained predominantly from Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP 2003, 2004). This chemical was assessed as part of a group assessment of isothiazolinones.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Methylisothiazolone has moderate acute oral and dermal toxicity and high acute inhalation toxicity, is corrosive to the skin, and is a skin sensitiser.

The critical adverse health effect of the chemical is skin sensitisation. In high concentrations, the chemicals are also corrosive.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) is 19 mg/kg bw/day based on decreased bodyweight and food and water consumption.

The chemical is not genotoxic. Based on read-across data available for a 3:1 mixture of methylchloroisothiazolinone and methylisothiazolone, the chemical is neither carcinogenic nor a reproductive toxicant.

23.3 Human exposure assessment

23.3.1 Worker exposure

Exposure of workers to methylisothiazolone is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual methylisothiazolone.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.109) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.109 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.030	0.001	0.031
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	1.32 x 10 ⁻⁵	1.15 x 10 ⁻⁷	1.33 x 10 ⁻⁵
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.031
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

23.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemicals to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.110) and children (Table D.111).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.110 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	1.670	N/A	1.670
Bathing in contaminated surface water	Negligible*	9.91 x 10 ⁻⁴	9.91 x 10 ⁻⁴
Swimming in contaminated surface water	1.24 x 10 ⁻⁴	9.91 x 10 ⁻⁴	1.11 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			1.672
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	4.482 x 10 ⁻⁴	N/A	4.482 x 10 ⁻⁴
Bathing in contaminated groundwater	Negligible*	2.49 x 10 ⁻⁷	2.49 x 10 ⁻⁷
Drinking contaminated surface water	8.14 x 10 ⁻⁸	N/A	8.14 x 10 ⁻⁸
Bathing in contaminated surface water	Negligible*	4.52 x 10 ⁻¹¹	4.52 x 10 ⁻¹¹
Swimming in contaminated surface water	6.04 x 10 ⁻¹²	4.83 x 10 ⁻¹¹	5.44 x 10 ⁻¹¹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			4.484 x 10 ⁻⁴
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			8.15 x 10 ⁻⁸

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.111 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	5.843	N/A	5.843
Bathing in contaminated surface water	Negligible*	1.72 x 10 ⁻³	1.72 x 10 ⁻³
Swimming in contaminated surface water	1.73 x 10 ⁻³	1.84 x 10 ⁻³	3.57 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			5.849
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.002	N/A	0.002
Bathing in contaminated groundwater	Negligible*	4.62 x 10 ⁻⁷	4.62 x 10 ⁻⁷
Drinking contaminated surface water	2.85 x 10 ⁻⁷	N/A	2.85 x 10 ⁻⁷
Bathing in contaminated surface water	Negligible*	8.39 x 10 ⁻¹¹	8.39 x 10 ⁻¹¹
Swimming in contaminated surface water	8.46 x 10 ⁻¹¹	8.96 x 10 ⁻¹¹	1.74 x 10 ⁻¹⁰
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.002
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			2.85 x 10 ⁻⁷

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

23.4 Human health risk characterisation

23.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

23.4.2 Occupational health risks

23.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical or its solution will result in adverse health effects such as acute dermal toxicity (at concentrations $\geq 25\%$), acute inhalation toxicity (at concentrations $\geq 3\%$), skin and eye irritation (at concentrations $\geq 0.06\%$), and skin sensitisation (at concentrations $\geq 0.01\%$). Given the concentration of the chemical as delivered to operational sites (assumed to be 5%), the chemical in this form is of low concern with regards to acute dermal toxicity for workers, but is of potential concern with regards to acute inhalation toxicity, skin and eye irritation, and skin sensitisation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

23.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is decreased bodyweight and decreased food and water consumption. The NOAEL established for this effect is 19 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.112).

Table D.112 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	607
Cleaning and maintenance (hydraulic fracturing)	1.43×10^6
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	606

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.109).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

23.4.3 Public Health Risks

23.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

23.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.113).

Table D.113 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	11	3
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	4.24×10^4	1.21×10^4
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	2.33×10^8	6.66×10^7

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.110 and Table D.111).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern (decreased bodyweight and food and water consumption) for adults and children from repeated exposures via environmental contamination from a bulk transport spill. MOEs for the storage pond leak scenario indicate a low concern for adverse health effects for this exposure scenario.

It should be noted that as much as some MOEs suggest potential risks of adverse health effects for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only

small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

23.4.4 Conclusions

23.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute inhalation toxicity, skin and eye irritation, and skin sensitisation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

23.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs are suggestive of a potential concern for adults and children based on the modelled exposure scenario of a bulk transport spill. Calculated MOEs indicate a low concern for adults and children from repeated exposures via environmental contamination from a leaking storage pond.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

23.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

23.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

23.5.2 Control measures available to minimise risks to the public

23.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

23.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- SCCNFP (2003) Opinion concerning Methylisothiazolinone Colipa n° P94. Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, SCCNFP/0625/02, final.
- SCCNFP (2004) Opinion concerning Methylisothiazolinone Colipa n° P94. Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, SCCNFP/0805/04.

D24 Carbonic acid, sodium salt (1:2)

CAS RN	CAS Name
497-19-8	Carbonic acid, sodium salt (1:2)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

24.1 Chemical use and concentration

The document from here on refers to Carbonic acid, sodium salt (1:2) (CAS RN 497-19-8) as 'sodium carbonate', one of the synonyms of the chemical.

Sodium carbonate is used as a component of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is as a pH buffer.

Prior to incorporation into the final drilling and hydraulic fracturing fluids, sodium carbonate as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 2 532 g/L (100%). After incorporation, it is present at a confidential business information (CBI) concentration in drilling fluid and at a default concentration of 10 g/L (1%) in hydraulic fracturing fluid. The industry survey did not note this chemical as being used in both drilling and hydraulic fracturing fluids at the same site.

24.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The information on health hazards is obtained from the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report on sodium carbonate (OECD 2002). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

When absorbed systemically, the chemical dissociates fully into sodium ions and bicarbonate ions. These are normal physiological constituents in humans which are regulated by homeostatic mechanisms. Carbonate ions are neutralised by gastric acids in the stomach but have the capacity to affect blood pH. High doses may cause alkalosis. Blood pH is efficiently regulated by mechanisms such as urinary excretion of bicarbonate and exhalation of carbon dioxide. Excess sodium is excreted predominantly via urine.

Sodium carbonate has low acute oral, dermal and inhalation toxicity. The acute oral median lethal dose (LD50) in rats is 2 800 mg/kg bw, while the dermal LD50 in rats is > 2 000 mg/kg bw. The LC50 in guinea pig, mice and rat are 800, 1 200 and 2 300 mg/m³ respectively. Sodium carbonate has low skin irritation potential. It is a moderate eye and respiratory irritant.

Information on repeated dose toxicity by the oral and dermal routes is not available. In rats, inhalation exposure to 2% sodium carbonate aerosol (70 mg/mg³) for over three months did not have any adverse effect. Histopathological changes in the respiratory tract and lungs seen following repeated inhalation exposure were considered local responses to the high alkalinity of this group of chemicals.

A No Observed Adverse Effect Level (NOAEL) was not available. Based on the absence of adverse effects observed in a repeat dose inhalation toxicity study, for the purposes of quantifying any potential health risk, the highest dose tested in the above study (70 mg/m³) is used in the human health risk assessment. This dose is likely to be a conservative estimate of a highest dose not causing adverse effects, as the maximum dose deliverable in a respiratory study is considerably less than can be delivered through an oral dosing study.

Sodium carbonate was not genotoxic or carcinogenic. Reproductive toxicity studies are not available; however, no effects on reproductive organs were noted when rats were exposed to sodium carbonate aerosol for over three months. Developmental studies with rats did not show any toxicity.

Eye and respiratory tract irritation are the critical adverse health effects for risk assessment.

24.3 Human exposure assessment

24.3.1 Worker exposure

Exposure of workers to sodium carbonate is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols or particulate chemical during operations. Exposure may also occur from contact with produced water containing residual potassium carbonate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.114) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling and hydraulic fracturing process is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.114 Internal doses resulting from sodium carbonate exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0	0.030	0.030
Mixing/blending of hydraulic fracturing chemicals	0	0.070	0.070

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	0	0.001	0.001
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.071
Produced water transport and storage	Negligible*	Negligible*	Negligible*
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} – Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and of produced water are negligible (NICNAS 2017a).

24.3.2 Public exposure

The public may be exposed to sodium carbonate via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming) – relates to both drilling and hydraulic fracturing operations
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming) – relates only to hydraulic fracturing operations
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming) – relates only to hydraulic fracturing operations
- emissions of aerosolised and particulate sodium carbonate to ambient air from operations – relates to both drilling and hydraulic fracturing operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to the chemical via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water for the different public exposure scenarios. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived from drilling operations for adults and children (Table D.115 and Table D.116) and from hydraulic fracturing operations for adults and children (Table D.117 and Table D.118).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.115 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.39	N/A	33.39
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	2.48 x 10 ⁻³	0	2.48 x 10 ⁻³
Combined exposure from bulk spill – surface water use			33.393
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (NICNAS 2017a).

Table D.116 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	3.47 x 10 ⁻²	0	3.47 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			116.900

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (NICNAS 2017a).

Table D.117 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	5.79	N/A	5.79
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	4.30 x 10 ⁻⁴	0	4.30 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			5.79
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	4.074	N/A	4.074
Bathing in contaminated groundwater	Negligible*	0	0
Drinking contaminated surface water	7.40 x 10 ⁻⁴	N/A	7.40 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	5.49 x 10 ⁻⁸	0	5.49 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use			4.074

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			7.40 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.118 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	20.264	N/A	20.264
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	6.01 x 10 ⁻³	0	6.01 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			20.270
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	14.260	N/A	14.260
Bathing in contaminated groundwater	Negligible*	0	0
Drinking contaminated surface water	2.59 x 10 ⁻³	N/A	2.59 x 10 ⁻³
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	7.69 x 10 ⁻⁷	0	7.69 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			14.260
Combined exposure from subsurface leak – surface water use			2.59 x 10 ⁻³

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; *E_{derm}* – Internal dose from dermal exposure; *E_{total}* – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

24.4 Human health risk characterisation

24.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

24.4.2 Occupational health risks

24.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as severe eye and respiratory irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites (100% pure chemical as a solid) are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed. Hence, there is a potential concern for acute adverse health effects occurring from the handling of the chemical as delivered to site.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. Drilling and hydraulic fluids containing 1% sodium carbonate are expected to be highly alkaline and acute exposure to these fluids is of potential concern for workers.

24.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 70 mg/m³.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.119).

Assuming 100% inhalation absorption, an average rat body weight of 350 grams, and a respiratory rate of 0.29 m³ of air (CalEPA 1997), this represents an internal absorbed dose of:

$$\frac{70 \text{ mg/m}^3 \times 0.29 \text{ m}^3/\text{day} \times 4 \text{ h}}{0.350 \text{ kg} \times 24 \text{ h}} = 9.67 \text{ mg/kg bw/day} \quad [\text{Equation D.5}]$$

Margins of Exposure (MOE) for adverse health effects from repeated occupational exposures in drilling and hydraulic fracturing operations are separately calculated by comparing the conservative, internal absorbed dose with exposures estimated for different occupational activities (Table D.119).

Table D.119 Margins of Exposure calculated for drilling and hydraulic fracturing different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of drilling chemicals	370
Mixing/blending of hydraulic fracturing chemicals	145
Cleaning and maintenance (drilling)	n.d.
Cleaning and maintenance (hydraulic fracturing)	9230
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	144

*n.d. – not disclosed. * MOEs for transport/storage, injection and drilling mud/produced water handling are not calculated due to negligible human exposures (Table D.114). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that sodium carbonate is of low concern for workers from repeated exposures during certain operations.

24.4.3 Public health risks

24.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

24.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 70 mg/m³, equivalent to 13.0 mg/kg bw/day.

Margins of Exposure (MOE) for adverse health effects were calculated for adults and children (see Table D.120 and Table D.121) by comparing this conservative, highest no-effect dose with exposures estimated for various scenarios outlined in Table D.115 to Table D.118.

Table D.120 Margins of Exposure calculated for different public exposure scenarios (drilling)

Public exposure scenario	Margin of Exposure (MOE)* (ADULT)	Margin of Exposure (MOE)* (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	0.3	0.1

* In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Table D.121 Margins of Exposure calculated for different public exposure scenarios (hydraulic fracturing)

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2	0.5
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	2	1
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	1.31×10^4	3732

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.117 and Table D.118). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling and toxicological studies that did not identify a dose of the chemical associated with adverse effects, the MOEs < 100 derived for repeated public exposures for some exposure scenarios suggest that a potential health concern cannot be ruled out for adults and children. However, when absorbed systemically the chemical dissociates into sodium and carbonate ions which are normal constituents of the human body regulated by homeostatic mechanisms. Overall, the chemical is therefore of low concern for the public for these exposure scenarios.

The MOEs > 100 based on conservative exposure modelling of environmental contamination from the leaking storage pond (surface water use) indicate a low concern for the public for this exposure scenario.

These scenarios assume public contact with contaminated water. The modelled PEC for accidental bulk spill of sodium carbonate (1 169 mg/L) translates into 0.01 M sodium carbonate which will have a pH of about 11. Individuals exposed to the contaminated water will experience eye irritation and therefore become aware of the contamination. This decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for repeated human exposure would be further reduced.

24.4.4 Conclusions

24.4.4.1 Occupational health risks

Sodium carbonate as delivered to operational sites is of potential concern for workers during operations based on the potential for severe eye and respiratory tract irritation.

Exposure to drilling or hydraulic fracturing fluid containing sodium carbonate is of potential concern due to the potential for eye irritation.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during drilling and hydraulic fracturing operations.

24.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, the chemical is of low concern for the public. Due to the high alkalinity expected of water contaminated in such a spill, eye irritation that may occur following initial bathing will likely mitigate against repeat exposures.

24.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

24.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

The risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

24.6 References

- CalEPA (California Environmental Protection Agency) (1997) Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels. Draft for Public Review. Office of Environmental Health Hazard Assessment, Air Toxicology and Epidemiology Section, Berkeley, CA.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2002) Screening Information Data Set (SIDS) Initial Assessment Report (SIAR) on sodium carbonate. Organisation for Economic Co-operation and Development (OECD), Paris. Accessed in April 2013 at <http://www.inchem.org/documents/sids/sids/Naco.pdf>

D25 1,3-Propanediol, 2-bromo-2-nitro-

CAS RN	CAS Name
52-51-7	1,3-Propanediol, 2-bromo-2-nitro-

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

25.1 Chemical use and concentration

The document from here on refers to 1,3-Propanediol, 2-bromo-2-nitro- (CAS RN 52-51-7) as 'bronopol', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a microbial control agent.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 1 000 g/kg (100%). After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

25.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the United States Environmental Protection Agency (US EPA) reregistration eligibility decision for bronopol (US EPA 1995).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Bronopol has moderate acute dermal and oral toxicity, is irritant to the skin and respiratory system, and corrosive to the eyes. The chemical is not a skin sensitiser in animals and humans.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment purposes is 10.4 mg/kg bw/day based on systemic effects.

The chemical is not genotoxic or a carcinogen based on available data. The NOAEL for fertility effects was 70 mg/kg bw/day. Developmental effects of the chemical were not observed in the absence of maternal toxicity.

25.3 Human exposure assessment

25.3.1 Worker exposure

Exposure of workers to bronopol is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of particulates/aerosols during operations. Exposure may also occur from contact with produced water containing residual bronopol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.122) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.122 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.600	0.026	0.626
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

25.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.123) and children (Table D.124).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.123 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
<i>Accidental bulk spill during transport and surface runoff</i>			
Drinking contaminated surface water	0.018	N/A	0.018
Bathing in contaminated surface water	Negligible*	1.07 x 10 ⁻⁵	1.07 x 10 ⁻⁵
Swimming in contaminated surface water	1.34 x 10 ⁻⁶	1.07 x 10 ⁻⁵	1.20 x 10 ⁻⁵
Combined exposure from bulk spill – surface water use			0.018

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking, bathing and swimming in contaminated surface water			
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.124 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.063	N/A	0.063
Bathing in contaminated surface water	Negligible*	1.86 x 10 ⁻⁵	1.86 x 10 ⁻⁵
Swimming in contaminated surface water	1.87 x 10 ⁻⁵	1.99 x 10 ⁻⁵	3.86 x 10 ⁻⁵
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.063

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all route. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

25.4 Human health risk characterisation

25.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

25.4.2 Occupational health risks

25.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as acute dermal toxicity, and skin, eye and respiratory irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

As the chemical is delivered to site as the 100% pure solid chemical, it is likely that such exposures will result in these acute adverse health effects.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

25.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is systemic toxicity. The NOAEL established for this effect is 10.4 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.125).

Table D.125 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	17
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.122).*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of potential concern for workers from repeated exposures during mixing / blending of hydraulic fracturing chemicals and from a combined exposure during mixing / blending and cleaning and maintenance. The MOE for cleaning and maintenance indicates that there is a low concern for systemic health effects for this activity alone. For fertility effects, MOEs indicate that the chemical is of low concern for any of the modelled occupational exposure scenarios.

25.4.3 Public health risks

25.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

25.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.126).

Table D.126 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	576	165
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.123 and Table D.124).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children (for systemic effects) from repeated exposures for the modelled exposure scenarios.

25.4.4 Conclusions

25.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute dermal toxicity, and skin, eye and respiratory irritation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during certain operations.

25.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

25.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

25.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires an amendment to the current classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

The risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

25.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- US EPA (1995) Reregistration Eligibility Document – Bronopol. United States Environmental Protection Agency, Office of Pesticide Programs, Case 2770, September 1995, Available as of March 2004.

D26 Phosphonium, tetrakis(hydroxymethyl)-, sulfate salt (2:1)

CAS RN	CAS Name
55566-30-8	Phosphonium, tetrakis(hydroxymethyl)-, sulfate salt (2:1)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

26.1 Chemical use and concentration

The document from here on refers to Phosphonium, tetrakis(hydroxymethyl)-, sulfate salt (2:1) (CAS RN 55566-30-8) as 'THPS', one of the synonyms of the chemical.

The chemical is used as a component of a drilling fluid formulation and a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the drilling fluid, the chemical as reported in supplementary industry information (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of up to 250 g/L. After incorporation, THPS is present in drilling fluid at a concentration of up to 0.357 g/L.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a CBI concentration. After incorporation, THPS is present in hydraulic fracturing fluid at a CBI concentration.

26.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the International Programme on Chemical Safety (IPCS 2000), the United States National Toxicology Program (US NTP 1987), and the International Agency for Research on Cancer (IARC 1990,1999).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

THPS has moderate acute oral and inhalation toxicity, low acute dermal toxicity, and is an eye irritant and a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment purposes is 3.6 mg/kg bw/day based on systemic effects involving the liver and spleen at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 7.2 mg/kg bw/day.

The chemical is neither genotoxic nor a carcinogen. THPS is not considered a developmental toxicant.

26.3 Human exposure assessment

26.3.1 Worker exposure

Exposure of workers to THPS is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual THPS.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.127) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling and hydraulic fracturing processes is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.127 Internal doses resulting from chemical exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drilling			
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.150	0.544	0.694
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	0.004	0.003	0.007
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			0.701
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*
Hydraulic fracturing			
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Drilling mud and produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and flowback/produced water are negligible (NICNAS 2017a).

26.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)

- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.128) and children (Table D.129).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.128 Internal doses for ADULTS associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (THPS in drilling product)			
Drinking contaminated surface water	0.668	N/A	0.668
Bathing in contaminated surface water	Negligible*	3.96 x 10 ⁻⁴	3.96 x 10 ⁻⁴
Swimming in contaminated surface water	4.96 x 10 ⁻⁵	3.96 x 10 ⁻⁴	4.46 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.669
Accidental bulk spill during transport and surface runoff (THPS in hydraulic fracturing product)			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.129 Internal doses for CHILDREN associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (THPS in drilling product)			
Drinking contaminated surface water	2.337	N/A	2.337

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated surface water	Negligible*	6.88 x 10 ⁻⁴	6.88 x 10 ⁻⁴
Swimming in contaminated surface water	6.94 x 10 ⁻⁴	7.35 x 10 ⁻⁴	1.43 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			2.339
Accidental bulk spill during transport and surface runoff (THPS in hydraulic fracturing product)			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

26.4 Human health risk characterisation

26.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

26.4.2 Occupational health risks

26.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to operational sites will result in adverse health effects such as acute inhalation toxicity, eye irritation, and skin sensitisation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low final concentrations in drilling and hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

26.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is systemic toxicity involving the liver and spleen. The NOAEL established for this effect is 3.6 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.130).

Table D.130 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Drilling	
Mixing/blending of drilling chemicals	5
Cleaning and maintenance (drilling)	487
Combined exposure	5
Mixing/blending and cleaning and maintenance (drilling)	
Hydraulic fracturing	
Mixing/blending of hydraulic fracturing chemicals	n.d.

Activity*	Margin of Exposure (MOE)
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.127).

For both drilling and hydraulic fracturing processes, based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical, as delivered to operational sites, is of potential concern for workers from repeated exposures during mixing / blending and during combined exposures from mixing / blending and cleaning and maintenance.

26.4.3 Public health risks

26.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

26.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.131).

Table D.131 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff (THPS in drilling product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	5	2
Accidental bulk spill during transport and surface runoff (THPS in hydraulic fracturing product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond (THPS in hydraulic fracturing product)		
Combined exposure from subsurface leak –	n.d.	n.d.

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water		
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.128 and Table D.129).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill (for drilling and hydraulic fracturing operations) and exposures to contaminated groundwater/surface water from a long-term leak from a storage pond.

It should be noted that as much as some MOEs suggest potential risks of adverse health effects for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

26.4.4 Conclusions

26.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute inhalation toxicity, eye irritation, and skin sensitisation.

Exposure to the chemical via drilling/hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during certain operations.

26.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of potential concern for adults and children in the event of a bulk transport spill (for drilling as well as hydraulic fracturing operations) and exposures to contaminated groundwater/surface water from a long-term leak from a storage pond.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

26.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

26.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

26.5.2 Control measures available to minimise risks to the public

26.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

26.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.

- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program

26.6 References

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- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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D27 Carbonic acid, potassium salt (1:2)

CAS RN	CAS Name
584-08-7	Carbonic acid, potassium salt (1:2)

27.1 Chemical use and concentration

The document from here on refers to Carbonic acid, potassium salt (1:2) (CAS RN 584-08-7) as 'potassium carbonate', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a buffering agent.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 500 g/L (50%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 10 g/L (1%).

27.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

When absorbed systemically, the chemical dissociates fully into potassium ions and bicarbonate ions. These are normal physiological constituents in humans which are regulated by homeostatic mechanisms. Carbonate ions are neutralised by gastric acids in the stomach but have the capacity to affect blood pH. High doses may cause alkalosis. Blood pH is efficiently regulated by mechanisms such as urinary excretion of bicarbonate and exhalation of carbon dioxide. Excess potassium is excreted predominantly via urine.

Potassium carbonate has low acute oral, dermal and inhalation toxicity. Potassium carbonate has low skin irritation potential. It is a severe eye irritant and is expected to be a moderate respiratory irritant based on repeat dose inhalation effects.

Information on repeated dose toxicity by the oral and dermal routes is not available. In rats, whole body exposure to up to 0.4 mg/L of a scrubbing solution aerosol, containing 30.8% potassium carbonate (0.12 mg/L), for 21 days did not result in any persistent systemic toxicity or neurotoxicity. Reversible histopathological changes noted in nasal cavities and lungs of treated animals were considered to be a local response to the alkalinity of the test material as substantiated by the return to normal upon cessation of exposure.

Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying any potential health risk the highest dose tested in the critical study

(0.12 mg/L) is used in this risk assessment. This dose is likely to be a conservative estimate of a highest dose not causing adverse effects, as the maximum dose deliverable in a respiratory study is considerably less than can be delivered through an oral dosing study.

Potassium carbonate was not genotoxic or carcinogenic. Reproductive toxicity studies are not available; however, no effects on reproductive organs were noted when rats were exposed to potassium carbonate aerosols. Developmental studies with rats did not show any toxicity. Overall the most sensitive effect from potassium carbonate is eye irritation.

27.3 Human exposure assessment

27.3.1 Worker exposure

Exposure of workers to potassium carbonate is possible via inadvertent spills and leaks, especially during any required manual handling. Exposure may also occur from contact with produced water containing residual potassium carbonate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.132) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.132 Internal doses resulting from potassium carbonate exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0	0.013	0.013
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0	0.001	0.001
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	0	0.014	0.014

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNA 2017b).

27.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosolised potassium carbonate to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to the chemical via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water for the different public exposure scenarios. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.133) and children (Table D.134).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.133 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	16.695	N/A	16.695
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	1.24 x 10 ⁻³	0	1.24 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			16.696
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	4.074	N/A	4.074
Bathing in contaminated groundwater	Negligible*	0	0
Drinking contaminated surface water	7.40 x 10 ⁻⁴	N/A	7.40 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	5.49 x 10 ⁻⁸	0	5.49 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			4.074
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			7.40 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.134 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	58.433	N/A	58.433
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	1.73 x 10 ⁻²	0	1.73 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			58.450
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	14.260	N/A	14.260
Bathing in contaminated groundwater	Negligible*	0	0
Drinking contaminated surface water	2.59 x 10 ⁻³	N/A	2.59 x 10 ⁻³
Bathing in contaminated surface water	Negligible*	0	0
Swimming in contaminated surface water	7.69 x 10 ⁻⁷	0	7.69 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			14.260
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			2.59 x 10 ⁻³

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

27.4 Human health risk characterisation

27.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

27.4.2 Occupational health risks

27.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site (50% solution) will result in adverse health effects such as eye and respiratory irritation.

Acute, inadvertent exposures to potassium carbonate as delivered to operational sites are most likely during its manual handling (if required) and during manipulation of equipment containing the residual potassium carbonate during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed. Hence, there is a potential concern for acute adverse health effects occurring from the handling of the chemical as delivered to site.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. Hydraulic fluid containing 1% potassium carbonate is expected to be highly alkaline and exposure to the hydraulic fluid is of potential concern for acute adverse health effects for workers.

27.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to potassium carbonate at any dose tested, up to 0.12 mg/L.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this conservative, highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.135).

Assuming 100% inhalation absorption, an average rat body weight of 215 grams, and a respiratory rate of 0.16 m³ of air per day (CalEPA 1997), this represents an internal absorbed dose of:

$$\frac{120\text{mg}/\text{m}^3 \times 0.29\text{m}^3 \times 6\text{h}}{0.35\text{kg} \times 24\text{h}} = 24.9\text{mg}/\text{kg bw}/\text{day} \quad [\text{Equation D.6}]$$

MOE for adverse health effects from repeated occupational exposures are calculated by comparing the internal absorbed dose with exposures estimated for different occupational activities during drilling (Table D.135).

Table D.135 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing fluid	1 900
Cleaning and maintenance (hydraulic fracturing)	23 770
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	1 760

* MOEs for transport, storage and produced water handling are not calculated due to negligible human exposures (Table D.132). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

27.4.3 Public health risks

27.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

27.4.3.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to potassium carbonate at any dose tested, up to 0.12 mg/L, equivalent to an internal dose of 22.3 mg/kg bw/day.

Margins of Exposure (MOE) for adverse health effects were calculated for adults and children (Table D.136) by comparing this conservative, highest no-effect dose with exposures estimated for various scenarios outlined in Table D.133 and Table D.134.

Table D.136 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2	0.4
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	6	2
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	3.36×10^4	9611

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.133 and Table D.134). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling and toxicological studies that did not identify a dose of the chemical associated with adverse effects, the MOEs < 100 derived for repeated public exposures for some exposure scenarios suggest that a potential concern cannot be ruled out for adults and children. However, when absorbed systemically the chemical

dissociates into potassium and carbonate ions which are normal constituents of the human body regulated by homeostatic mechanisms. Overall, the chemical is therefore of low concern for the public for these exposure scenarios.

The MOEs > 100 based on conservative exposure modelling of environmental contamination from the leaking storage pond (surface water use) indicate a low concern for the public for this exposure scenario.

These scenarios assume public contact with contaminated water. Noting that levels above 340 mg/L potassium affect the taste of water (Alberta Health and Wellness 2014), the modelled PEC for accidental bulk spill of potassium carbonate (584 mg/L) is equivalent to approximately 330 mg potassium which is almost at this taste threshold. This means that individuals exposed to the chemical in contaminated water may be able to detect the contamination, reducing the potential for repeated human exposures.

27.4.4 Conclusions

27.4.4.1 Occupational health risks

Potassium carbonate as delivered to operational sites is of potential concern for workers during operations based on the potential for eye and respiratory tract irritation.

Exposure to the hydraulic fracturing fluid containing potassium carbonate is of potential concern regarding possible eye irritation in workers due to high alkalinity.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during hydraulic fracturing operations. However, eye irritation from acute and repeated exposure to these fluids is possible.

27.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures via environmental contamination, the chemical is of low concern for the public. Repeated exposures are regarded as unlikely due to the chemical being at a high enough concentration to affect the taste of the contaminated water.

27.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

27.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals.

Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

27.6 References

- Alberta Health and Wellness (2014) Environmental Public Health Field Manual for Private, Public and Communal Drinking Water Systems in Alberta. Second Edition, 2004. Accessed March 2015. <http://www.health.alberta.ca/documents/Drinking-Water-Systems-2004.pdf>
- CalEPA (1997) Technical Support Document for the Determination of Noncancer Chronic Reference Exposure Levels, Draft for Public Review, California Environmental Protection Agency (CalEPA) Office of Environmental Health Hazard Assessment, Air Toxicology and Epidemiology Section, Berkeley, CA.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on potassium carbonate (CAS RN 584-08-7). European Union. Accessed October 2013 <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D28 Glycine, N,N'-1,2-ethanediylbis[N (carboxymethyl)-, sodium salt (1:4)]

CAS RN	CAS Name
64-02-8	Glycine, N,N'-1,2-ethanediylbis[N (carboxymethyl)-, sodium salt (1:4)]

28.1 Chemical use and concentration

The document from here on refers to glycine, N,N'-1,2-ethanediylbis[N(carboxymethyl)-, sodium salt (1:4)] (CAS No: 64-02-8) as 'tetrasodium EDTA', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a chelating agent.

No identity or concentration data were provided for tetrasodium EDTA in the coal seam gas industry survey (NICNAS 2017c). A reference to the safety data sheet (SDS) for a chelating/iron control agent U042 (Schlumberger 2011) listed its use as a corrosion inhibitor in hydraulic fracturing in Australia (QGC 2012). The SDS lists tetrasodium EDTA as the major component present in the product at a concentration of 30-60%. Therefore, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled within a liquid product at a concentration of 600 g/L (60%).

No data were provided in the industry survey for the final concentration of tetrasodium EDTA in fracturing fluid prior to use. The concentration was estimated based on the following information on the proportions of different additives used in fracturing fluids (Government of South Australia 2012).

- Iron control agent present at 0.004%
- Corrosion inhibitor present at 0.002%

The assumption that tetrasodium EDTA is used as an iron control agent is consistent with its description in the SDS and is also consistent with its ability to chelate metal ions. On this basis, it is estimated that the amount of tetrasodium EDTA compared to the total volume of injected hydraulic fracturing fluids is 0.04 g/L (0.004%).

28.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was sourced primarily from the Registration, Evaluation, Authorisation and Restriction of Chemicals dossier for tetrasodium EDTA (REACH 2013), a European Union Risk Assessment Report for tetrasodium EDTA (ECB 2005), a science assessment for EDTA chemicals (US EPA 2006) and an Organisation for Economic Co-operation and Development Screening Information Dataset Initial Assessment Profile for aminocarboxylic acid-based chelants (OECD 2012).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Only limited toxicity data were available for tetrasodium EDTA. Reliable data for disodium EDTA (CAS RN 139-33-3) and trisodium EDTA (CAS RN 150-38-9), both analogues of the tetrasodium compound, were available for the majority of the toxicity endpoints. All compounds have an identical chemical structure and functional groups, differing only in the extent of ionisation of the four carboxylic acid groups. Data available for the disodium and trisodium compounds are used to read-across to the endpoints for tetrasodium EDTA.

Tetrasodium EDTA is harmful by the oral route. This potential for acute toxicity was also demonstrated by the inhalation route based on data available for disodium EDTA. The chemical is not irritating to the skin but is a severe eye irritant in animals. Limited data for disodium EDTA suggest exposure to aerosols may cause adverse effects with a Lowest-Observed-Adverse-Effect-Concentration (LOAEC) of 30 mg/m³ established for laryngeal necrosis and regenerative hyperplasia of bronchi at the lowest dose. It is therefore likely that tetrasodium EDTA is a respiratory irritant. Based on data available for disodium EDTA, tetrasodium EDTA is not a skin sensitiser.

Tetrasodium EDTA has not been tested for its repeated dose toxicity. However, supporting data available for the other sodium salts indicate a low potential for toxicity after repeated oral administration. Specifically, toxicity data for disodium EDTA were used for evaluation of the critical (most sensitive) health effect for repeated exposures to the chemical. In a 13-week dietary study in rats, disodium EDTA was associated with systemic effects involving increased mortality, reduced bodyweight gain, diarrhoea and emaciation. The No Observed Adverse Effect Level (NOAEL) established for these effects (692 mg/kg bw/day) is taken through to the risk assessment for tetrasodium EDTA.

It should be noted, however, that this NOAEL may be conservative (unnecessarily low) as the next dose in the study, which was identified as the Lowest Observed Adverse Effect Level (LOAEL) for these systemic effects, was approximately six times that of the NOAEL, namely 4 206 mg/kg bw/day. This gap between the two dosing levels is unusually large, and had intermediate doses been tested, a higher (less conservative) NOAEL than 692 mg/kg bw/day may have been identified.

The chemical is not genotoxic or a developmental toxicant and, based on data for trisodium and disodium EDTA respectively, is not a carcinogen or toxic to fertility.

The critical adverse health effect of tetrasodium EDTA for risk characterisation is likely to be its inhalation toxicity.

28.3 Human exposure assessment

28.3.1 Worker exposure

Exposure of workers to tetrasodium EDTA is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual tetrasodium EDTA.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to

operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.137) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.137 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	3.60 x 10 ⁻⁶	0.016	0.016
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	4.80 x 10 ⁻⁹	4.19 x 10 ⁻⁶	4.20 x 10 ⁻⁶
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.016
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

28.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)

- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.138) and children (

Table D.139).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.138 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	1.002	N/A	1.002
Bathing in contaminated surface water	Negligible*	1.19 x 10 ⁻⁷	1.19 x 10 ⁻⁷
Swimming in contaminated surface water	7.43 x 10 ⁻⁵	1.19 x 10 ⁻⁷	7.44 x 10 ⁻⁵
Combined exposure - Drinking/bathing/swimming in contaminated surface water			1.002
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater		N/A	0.001

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
	0.001		
Bathing in contaminated groundwater	Negligible*	9.05 x 10 ⁻¹¹	9.05 x 10 ⁻¹¹
Drinking contaminated surface water	1.48 x 10 ⁻⁷	N/A	1.48 x 10 ⁻⁷
Bathing in contaminated surface water	Negligible*	1.64 x 10 ⁻¹⁴	1.64 x 10 ⁻¹⁴
Swimming in contaminated surface water	1.10 x 10 ⁻¹¹	1.76 x 10 ⁻¹⁴	1.10 x 10 ⁻¹¹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.001
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			1.48 x 10 ⁻⁷

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. *Oral exposures associated with bathing are negligible (see NICNAS, 2017b). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.139 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill and surface runoff			
Drinking contaminated surface water	3.506	N/A	3.506
Bathing in contaminated surface water	Negligible*	2.06 x 10 ⁻⁷	2.06 x 10 ⁻⁷
Swimming in contaminated surface water	1.04 x 10 ⁻³	2.21 x 10 ⁻⁷	1.04 x 10 ⁻³
Combined exposure – Drinking/bathing/swimming in contaminated surface water			3.507
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.003	N/A	0.003
Bathing in contaminated groundwater	Negligible*	1.68 x 10 ⁻¹⁰	1.68 x 10 ⁻¹⁰
Drinking contaminated surface water	5.18 x 10 ⁻⁷	N/A	5.18 x 10 ⁻⁷

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated surface water	Negligible*	3.05 x 10 ⁻¹⁴	3.05 x 10 ⁻¹⁴
Swimming in contaminated surface water	1.54 x 10 ⁻¹⁰	3.26 x 10 ⁻¹⁴	1.54 x 10 ⁻¹⁰
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.003
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			5.18 x 10 ⁻⁷

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

28.4 Human health risk characterisation

28.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

28.4.2 Occupational health risks

28.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects, such as respiratory irritation and the risk of serious eye damage. Given the assumed concentration of the chemical as delivered to operational sites (600 g/L or 60%), the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.04 g/L or 0.004%), exposure to the chemical via these fluids is of low concern for workers.

28.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to an analogue chemical, disodium EDTA, are systemic effects associated with increased mortality, reduced bodyweight gain, diarrhoea and emaciation in rats. The conservative NOAEL established for these effects is 692 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.140).

Table D.140 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	4.40×10^4
Cleaning and maintenance (hydraulic fracturing)	1.65×10^8
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	4.40×10^4

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.137).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

28.4.3 Public health risks

28.4.3.1 Acute health risks

Given industrial use of tetrasodium EDTA for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

28.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and conservative NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.141).

Table D.141 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	691	197

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	8.49 x 10 ⁵	2.43 x 10 ⁵
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	4.68 x 10 ⁹	1.34 x 10 ⁹

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.138 and

Table D.139).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

28.4.4 Conclusions

28.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for respiratory irritation and serious eye damage.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposure during operations.

28.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites, and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

28.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

28.5.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017a), the chemical requires an amendment to the current classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017b).

28.6 References

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D29 2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy-

CAS RN	CAS Name
6410-41-9	2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy-

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

29.1 Chemical use and concentration

The document from here on refers to 2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy- (CAS RN 6410-41-9) as 'Pigment Red 5', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its reported function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a solid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

29.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Limited health hazard data were available for Pigment Red 5. Therefore, read-across of data from several structurally similar azo pigments was used to build a human health hazard profile for the chemical. These data were obtained predominantly from a group assessment of monoazo pigments by Environment Canada / Health Canada (Environment Canada / Health Canada 2013) and the Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers of monoazo pigments (REACH 2013a, 2013b, 2013c).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

On the basis of analogue data, Pigment Red 5 is expected to be of low acute oral and dermal toxicity (LD50 > 5000 mg/kg bw). No acute inhalation toxicity data were available. Also, it is not a skin irritant, nor is it expected to be an eye irritant or a skin sensitiser.

Repeat dose toxicity studies for structurally similar analogues noted no adverse effects with oral doses of approximately 1 000-1 250 mg/kg bw/day.

A majority of analogue genotoxicity studies reported negative results. Both positive and negative results were reported for analogues containing functional groups known to be associated with genotoxicity. Overall, Pigment Red 5 is not regarded as mutagenic.

A single carcinogenicity study was available for an analogue containing functional groups likely to give rise to metabolites known to be carcinogenic. Despite the presence of such groups, the study only reported equivocal evidence of carcinogenic activity in rats. No evidence of carcinogenicity was seen in mice. Consequently, Pigment Red 5, which lacks these functional groups and so cannot produce these carcinogenic metabolites, is not regarded as carcinogenic.

Analogue reproductive toxicity studies reported no adverse effects at doses of 1 000 mg/kg bw/day (highest dose tested).

Chronic toxicity studies produced no adverse effects, even at the highest dose tested. Hence, the No-Observed-Adverse-Effect Level (NOAEL) for risk assessment is the highest dose tested (1 000 mg/kg bw/day) across analogue studies for both repeat dose toxicity and reproductive toxicity.

29.3 Human exposure assessment

29.3.1 Worker exposure

Exposure of workers to Pigment Red 5 is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemicals/particulates during operations. Exposure may also occur from contact with produced water containing residual Pigment Red 5.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.142) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.142 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

29.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.143) and children (Table D.144).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.143 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak –			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.144 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
plus swimming in contaminated surface water			
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

29.4 Human health risk characterisation

29.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

29.4.2 Occupational health risks

29.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical is unlikely to result in adverse health effects. Therefore, the chemical as delivered to the site is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

29.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 1 000 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.145).

Table D.145 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.142). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in the hydraulic fracturing fluid, repeated exposure to the chemical via these fluids is of low concern for workers.

29.4.3 Public health risks

29.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

29.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.146).

Table D.146 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.143 and

Table D.144). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

29.4.4 Conclusions

29.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the chemical as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

29.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

29.5 Risk mitigation measures

Pigment Red 5 is not classified as a hazardous substance. Conservative risk assessment of the chemical indicated a low concern for workers and the public from the use of this chemical in coal seam gas operations. No specific risk mitigation measures are therefore indicated. However, best practice chemical management should always be implemented to minimise human exposure.

29.6 References

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D30 Ethanol

CAS RN	CAS Name
64-17-5	Ethanol

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

30.1 Chemical use and concentration

The chemical is used as a component of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final drilling and hydraulic fracturing fluids, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at concentrations of 100 g/L (10%) for drilling and 300 g/L (30%) for hydraulic fracturing. After incorporation, it is present in drilling fluid at a concentration of 10 g/L (1%) and in hydraulic fracturing fluid at CBI concentration.

30.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

The information on health hazards of ethanol is obtained from the following sources: an International Agency for Research on Cancer (IARC) summary and evaluation of alcohol drinking (IARC 1988), an IARC monograph on alcohol consumption and ethyl carbamate (IARC 2010), Organisation for Economic Co-operation and Development Initial Assessment Report on ethanol (OECD 2005) and Hazardous Substances Data Bank (US National Library of Medicine 2013). In addition, data were also obtained from registration dossiers on ethanol submitted by industry under the EU Registration, Evaluation, Authorisation and Restriction of Chemicals program (REACH 2013a, 2013b, 2013c).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Ethanol has low acute toxicity by all exposure routes. It is not irritating to skin but is irritating to eyes. It is not a skin sensitiser.

Ethanol has low repeat dose oral toxicity. The critical study for oral repeat dose effects is a 90-day drinking water study which established a No-Observed-Adverse-Effect Level (NOAEL) of 2 400 mg/kg bw/day. The Lowest-Observed-Adverse-Effect Level (LOAEL) was 3 600 mg/kg bw/day based on hepatic effects.

In *in vitro* genotoxicity tests, ethanol was shown not to be mutagenic in bacteria, mutagenic in animal cells or clastogenic in human or animal cells. In *in vivo* tests, ethanol was not mutagenic or clastogenic in animals in the majority of studies. Overall, data do not suggest that ethanol is a mutagen.

Although there are some reports of increased incidence of hepatocellular neoplasms with oral exposures to ethanol, the majority of oral repeat dose studies with ethanol failed to show

increases in tumour incidence. In humans, regular consumption of alcoholic beverages is associated with increased risk of malignant tumours of the oral cavity, pharynx, larynx, oesophagus, liver, colorectum and female breast. Accordingly, there is sufficient evidence for the carcinogenicity of alcoholic beverages in humans.

Current data indicate that, other than at very high doses, ethanol is not associated with effects on fertility. Developmental effects have been reported for ethanol in some, but not all, animal studies. Consequently, other than at very high doses, ethanol is not regarded as a developmental toxin.

Overall, the most sensitive endpoint for ethanol is repeat dose toxicity. The oral NOAEL was 2 400 mg/kg bw/day. This NOAEL is used in this human health risk assessment.

30.3 Human exposure assessment

30.3.1 Worker exposure

Exposure of workers to ethanol is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of volatilised chemical/aerosol during operations. Exposure may also occur from contact with produced water containing residual ethanol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.147) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling and hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.147 Internal doses resulting from ethanol exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.006	0.025	0.03
Mixing/blending of hydraulic fracturing chemicals	0.018	0.074	0.09
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	0.012	0.01	0.02
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			0.050
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

30.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised ethanol to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to ethanol via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.148) and children (

Table D.149) for drilling and adults (

Table D.150) and children (

Table D.151) for hydraulic fracturing.

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.148 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻⁴	1.98 x 10 ⁻⁴
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻⁴	4.46 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use			3.340
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a)

Table D.149 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻⁴	3.44 x 10 ⁻⁴
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻⁴	3.84 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.691

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

Table D.150 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	5.95 x 10 ⁻⁴	5.95 x 10 ⁻⁴
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	5.95 x 10 ⁻⁴	1.34 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			10.019
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.151 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.060	N/A	35.060
Bathing in contaminated surface water	Negligible*	1.03 x 10 ⁻³	1.03 x 10 ⁻³
Swimming in contaminated surface water	1.04 x 10 ⁻²	1.10 x 10 ⁻³	1.15 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			35.072
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; *E_{derm}* - Internal dose from dermal exposure; *E_{total}* - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

30.4 Human health risk characterisation

30.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

30.4.2 Occupational health risks

30.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site – 100 g/L (10%) for drilling and 300 g/L (30%) for hydraulic fracturing – is of potential concern for workers for adverse health effects such as eye irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling and hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

30.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is based on dose related effects on the liver. The NOAEL established for this effect is 2 400 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.152).

Table D.152 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	7.8×10^4
Mixing/blending of hydraulic fracturing chemicals	2.6×10^4
Cleaning and maintenance (drilling)	1.1×10^5
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	4.6×10^4
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection, handling of drilling muds and produced water are not calculated due to negligible human exposures (Table D.147).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the chemical in the drilling and hydraulic fracturing fluids repeated exposure to the chemical via these fluids is of low concern for workers.

30.4.3 Public health risks

30.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

30.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.153 and

Table D.154 for drilling and hydraulic fracturing respectively).

Table D.153 Margins of Exposure calculated for different public exposure scenarios (drilling)

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface	719	205

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
water		

Table D.154 Margins of Exposure calculated for different public exposure scenarios (hydraulic fracturing)

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	240	68
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (

Table D.150 and

Table D.151).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that ethanol is of low concern for adults from repeated exposures based on the modelled exposure scenarios. For children, MOEs suggestive of a potential concern were derived for only one exposure scenario, an accidental bulk transport spill for hydraulic fracturing operations.

NICNAS notes that industry reports it is common practice to separately transport the same chemical destined for use in drilling and in hydraulic fracturing operations. Hence it is unlikely these two lots of chemical would be involved in the same transport accident, and therefore the calculation of separate MOEs for a bulk spill of chemical separately destined for use in these two operations is valid.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

30.4.4 Conclusions

30.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for eye irritation.

Exposure to the chemical via drilling and hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via drilling and hydraulic fracturing fluids is of low concern for workers.

30.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults based on the modelled exposure scenarios. For children, risk estimates suggest a potential concern for the exposure scenario of an accidental bulk transport spill of the chemical for hydraulic fracturing operations.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

30.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

30.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the

chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

30.5.2 Control measures available to minimise risks to the public

30.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

30.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

30.6 References

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D31 Acetic acid

CAS RN	CAS name
64-19-7	Acetic acid

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

31.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a buffering agent. Some other functions of the chemical are confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 1 050 g/L (100%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.525 g/L (0.053%).

31.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on the health hazards of acetic acid was obtained predominantly from Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Acetic acid has low acute oral and inhalation toxicity and moderate dermal toxicity. The median lethal doses (LD50) for oral, dermal and inhalation routes were > 3 100 mg/kg bw, 1 060 mg/kg bw and 13.8 mg/L, respectively, in laboratory animals. Acetic acid is corrosive to the skin and eyes and its vapours cause irritation of the eyes, nose, throat and the lungs. The moderate acute dermal toxicity is believed to be due to its local corrosive effects rather than any systemic toxicity. Data on the sensitisation potential of acetic acid in animals are not available, although some reports suggest that acetic acid could cause skin sensitisation in humans (NIOSH 2010).

Acetic acid has low repeat dose toxicity by oral and dermal routes. Information on toxicity by the inhalation route is not available. In a rat oral repeat dose study, no systemic treatment-related effects were observed up to a dose of 1 200 mg/kg bw/day. It is not genotoxic or carcinogenic and does not have any developmental effects in animals. Information on effects on fertility is not available.

Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying any potential health risk, the highest dose tested in the critical study (1 200 mg/kg bw/day) is used in this risk assessment.

Overall the most sensitive effect from acetic acid exposure is its corrosivity.

31.3 Human exposure assessment

31.3.1 Worker exposure

Exposure of workers to acetic acid is possible via inadvertent spills and leaks, especially during any required manual handling and emissions of the volatilised chemical or its aerosol during operations. Exposure may also occur from contact with produced water containing residual acetic acid.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.155) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.155 Internal doses resulting from acetic acid exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.630	0.337	0.967
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.006	0.001	0.007
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.974
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

31.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised acetic acid to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for acetic acid levels in ambient air. Exposures of the public to the chemical via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

Conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water for the different public exposure scenarios. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.156) and children (Table D.157).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and the modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.156 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.06	N/A	35.06
Bathing in contaminated surface water	Negligible*	2.08×10^{-2}	2.08×10^{-2}
Swimming in contaminated surface water	2.60×10^{-3}	2.08×10^{-2}	2.34×10^{-2}
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			35.104
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.214	N/A	0.214
Bathing in contaminated groundwater	Negligible*	1.19×10^{-4}	1.19×10^{-4}
Drinking contaminated surface water	3.89×10^{-5}	N/A	3.89×10^{-5}
Bathing in contaminated surface water	Negligible*	2.16×10^{-8}	2.16×10^{-8}
Swimming in contaminated surface water	2.88×10^{-9}	2.31×10^{-8}	2.59×10^{-8}
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.214
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			3.89×10^{-5}

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.157 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	122.708	N/A	122.708
Bathing in contaminated surface water	Negligible*	3.61 x 10 ⁻²	3.61 x 10 ⁻²
Swimming in contaminated surface water	3.64 x 10 ⁻²	3.86 x 10 ⁻²	7.50 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			122.820
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.749	N/A	0.749
Bathing in contaminated groundwater	Negligible*	2.20 x 10 ⁻⁴	2.20 x 10 ⁻⁴
Drinking contaminated surface water	1.36 x 10 ⁻⁴	N/A	1.36 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	4.00 x 10 ⁻⁸	4.00 x 10 ⁻⁸
Swimming in contaminated surface water	4.04 x 10 ⁻⁸	4.28 x 10 ⁻⁸	8.31 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.749
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			1.36 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

31.4 Human health risk characterisation

31.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

31.4.2 Occupational health risks

31.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site (i.e. pure chemical) will result in adverse health effects, such as severe burns to skin and respiratory system and damage to the eyes and, possibly, skin sensitisation.

Acute, inadvertent exposures to the chemical as delivered to the operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance, and during clean-up of spills. Levels of exposure will vary depending on the work practices employed. Hence, there is a potential concern for acute adverse health effects from the handling of the chemical as delivered to site.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to concentrated chemical, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (0.053%), exposure to the chemical via these fluids is of low concern for workers.

31.4.2.2 Long-term health risks

From the hazard characterisation, there were no adverse health effects observed from repeated exposures to the chemical at any dose tested, up to 1 200 mg/kg bw/day.

Margins of Exposure (MOEs) for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities (Table D.158).

Table D.158 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	1240
Cleaning and maintenance (hydraulic fracturing)	1.72 x 10 ⁵
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	1 230

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.155). ** In the absence of a No-Observed-Adverse-Effect Level (NOAEL), these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to the operational site is of low concern for workers from repeated exposures during certain operations.

31.4.3 Public health risks

31.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

31.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the highest dose at which no adverse effects were noted in the oral repeat dose study (1 200 mg/kg bw/day), MOEs were calculated for adults and children for various exposure scenarios (Table D.159).

Table D.159 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill from transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	34	10
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	5607	1602
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	3.08×10^7	8.82×10^6

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.156 and Table D.157). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOEs < 100 derived for repeated public exposures for the scenario of accidental transport spill a potential concern cannot be ruled out for adults and children. In contrast, the MOEs > 100 for the other modelled scenarios indicate a low concern for adults and children for these scenarios.

These scenarios assume public contact with contaminated water. Noting that acetic acid (vinegar) has a taste threshold in humans of between 300 and 1 000 ppm (Virginia

Department of Health 1994), the modelled PEC for accidental bulk spill of acetic acid (1 227 mg/L) is above this taste threshold, meaning that individuals exposed to the chemical in contaminated water would be able to taste the acetic acid, and therefore become aware of the contamination. This decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for repeated human exposure would be further reduced.

31.4.4 Conclusions

31.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for causing severe burns to skin and respiratory system and damage to the eyes. Skin sensitisation effects are also possible.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

31.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk spill, based on the MOEs a potential concern cannot be ruled out for adults and children. For other exposure scenarios, risk estimates indicated a low concern for adults and children.

31.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

31.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

31.5.2 Control measures available to minimise risks to the public

31.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

31.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling do not allow a definitive conclusion regarding the level of concern for the public from contamination of surface water from a transport spill.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

31.6 References

- ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation Version 2.1 November 2012, European Chemicals Agency (ECHA).
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals

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Virginia Department of Health (1994) Acetic acid. Virginia Department of Health. Division of Health Hazards Control, USA. Available at <http://www.vdh.virginia.gov/epidemiology/dee/publichealthtoxicology/documents/pdf/aceticacid.pdf>

D32 Deodorised kerosene

CAS RN	CAS Name
64742-47-8	Distillates (petroleum), hydrotreated light

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

32.1 Chemical use and concentration

The document from here on refers to Distillates (petroleum), hydrotreated light (CAS RN 64742-47-8) as 'deodorised kerosene', one of the synonyms of the chemical.

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI). Prior to incorporation into the final drilling fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 600 g/L (60%). After incorporation, it is present in drilling fluid at a CBI concentration.

32.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the American Petroleum Institute (API 2010), Organisation for Economic Co-operation and Development (OECD 2011, 2012), and the Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers (REACH 2013). Data gaps for the substance are read-across from data available for kerosine (petroleum) (CAS RN 8008-20-6).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Deodorised kerosene is an aspiration hazard since it has low viscosity and is composed of aliphatic and aromatic hydrocarbons up to 10%.

Deodorised kerosene has low acute oral, dermal and inhalation toxicity, and is slightly irritating to the skin and eyes. The substance is not a skin sensitiser, based on reading across data available for kerosine (petroleum).

No treatment-related effects were reported in repeated oral and inhalation exposures to deodorised kerosene. Prolonged dermal exposure to kerosine (petroleum) reported local irritation in rats and rabbits, and changes in bodyweight and organ weights in rabbits. It is expected that these effects would be similar for deodorised kerosene. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk to the general worker and public, the highest dose tested in the study conducted in rats (1 000 mg/kg bw/day) is used in this risk assessment.

The substance is not genotoxic. It is neither a carcinogen nor a reproductive toxicant, based on reading across data available for kerosine (petroleum).

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment is 1 000 mg/kg bw/day based on maternal toxicity (decreased bodyweight gain) at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 1 500 mg/kg bw/day from a developmental toxicity study on kerosine (petroleum). This NOAEL will be used for deodorised kerosene in relation to pregnant workers and pregnant members of the public.

32.3 Human exposure assessment

32.3.1 Worker exposure

Exposure of workers to deodorised kerosene is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.160) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.160 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.036	0.450	0.486
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via the transport and storage of drilling muds are negligible (NICNAS 2017a).

32.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of ambient air and water used for drinking, bathing and recreation (e.g. swimming).

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the volatilised chemical/aerosols to ambient air from operations.

Swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, this public exposure scenario is included here.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air may be low compared to exposures via environmental waters. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not considered further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.161) and children (Table D.162).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.161 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	18.151	N/A	18.151
Bathing in contaminated surface water	Negligible*	1.08 x 10 ⁻³	1.08 x 10 ⁻³
Swimming in contaminated surface water	1.35 x 10 ⁻³	1.08 x 10 ⁻³	2.42 x 10 ⁻³
Combined exposure from bulk spill – surface water use			18.154
Drinking, bathing and swimming in contaminated			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.162 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	63.528	N/A	63.528
Bathing in contaminated surface water	Negligible*	1.87 x 10 ⁻³	1.87 x 10 ⁻³
Swimming in contaminated surface water	1.89 x 10 ⁻²	2.00 x 10 ⁻³	2.09 x 10 ⁻²
Combined exposure from bulk spill – surface water use			63.551
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for surface water (NICNAS 2017a).

32.4 Human health risk characterisation

32.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

32.4.2 Occupational health risks

32.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for workers, despite its concentration as delivered to site being relatively high (600 g/L, 60%).

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, exposure to the chemical via these fluids is of low concern for workers.

32.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect is maternal toxicity (decreased bodyweight gain). The NOAEL established for this effect is 1 000 mg/kg bw/day from a reproductive toxicity study. This NOAEL is applicable for pregnant workers.

There are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 1 000 mg/kg bw/day. This highest no-effect dose is applicable for a general worker.

Margins of Exposure (MOE) for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for maternal toxicity and the highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.163).

Table D.163 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE) for pregnant workers	Margin of Exposure (MOE)** for general workers
Mixing/blending of drilling chemicals	2.06 x 10 ³	2.06 x 10 ³
Cleaning and maintenance (drilling)	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection, handling of drilling muds are not calculated due to negligible human exposures (Table D.187). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

32.4.3 Public health risks

32.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

32.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, and the highest no-effect dose, MOEs were calculated for pregnant individuals (Table D.164) and the general population (Table D.165) for various exposure scenarios.

Table D.164 Margins of Exposure calculated for the drilling public exposure scenario for pregnant individuals

Public exposure scenario	Margin of Exposure (MOE) for pregnant individuals
Accidental bulk spill during transport and surface runoff	
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	55

Table D.165 Margins of Exposure calculated for the drilling public exposure scenario for the general population

Public exposure scenario*	Margin of Exposure (MOE)* (ADULT)	Margin of Exposure (MOE)* (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	55	16

* In the absence of a NOAEL, these MOEs were calculated based on the highest available dose. For this chemical, the highest dose tested for repeat dose toxicity did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs (Table D.5) for pregnant individuals are suggestive of a health concern (decreased bodyweight gain) from repeated exposures based on an accidental bulk transport spill.

For the general public (non-pregnant adults and children), the MOEs are also suggestive of a potential concern. However, the toxicological studies in animals on which this MOE is based did not demonstrate any adverse effects at any of the doses examined. Given the magnitude of the MOE, a potential concern for adults and children cannot be ruled out.

It should also be noted that as much as some MOEs suggest a potential concern for adverse health effects for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

32.4.4 Conclusions

32.4.4.1 Occupational health risks

Given the lack of acute adverse health effects relevant for workers, the chemical as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via drilling fluids is of low concern for workers.

32.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk transport spill, calculated MOEs are suggestive of a potential concern for pregnant individuals. For repeated exposures of non-pregnant adults and children for this scenario, calculated MOEs suggest a potential concern.

These public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

32.4.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

32.4.6 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

32.4.7 Control measures available to minimise risks to the public

32.4.7.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk

mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

32.5 References

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- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- OECD (2012) Screening Information Data Set (SIDS) Initial Assessment Profile for CoCAM 3: C9-C14 aliphatic [$\leq 2\%$ aromatic] hydrocarbon solvents category. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database. Accessed 9 December 2013 at http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=03fcd2e3-c65e-4499-a680-338a1c3c9c50&idx=0
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D33 Methanol

CAS RN	CAS Name
67-56-1	Methanol

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

33.1 Chemical use and concentration

Methanol is used as a component of drilling as well as hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final drilling and hydraulic fracturing fluids, methanol as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 100 g/L (10%). After incorporation, it is present in drilling fluid at a CBI concentration and in hydraulic fracturing fluid at a CBI concentration.

33.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The information on health hazards is obtained from the OECD Screening Information Data Set Initial Assessment Report on methanol (OECD 2004), Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers on the chemical (REACH 2013) and published papers.

Methanol has low acute oral, dermal and inhalation toxicity in experimental animals but moderate to high acute oral and dermal toxicity in humans. A Lowest Lethal Dose (LDLo) of 143 - 428 mg/kg bw (humans) has been reported. It is not a skin or eye irritant but is expected to be a moderate respiratory irritant, based on its effect on the mucous membrane in rats exposed to methanol vapours and on the effects observed in repeat dose inhalation studies. Tests with guinea pigs indicated that methanol is not a skin sensitiser.

The critical effects to human health are acute toxicity from inhalation, skin contact and swallowing, and possible irreversible effects from acute oral exposure. No deaths were reported in Rhesus monkeys dosed at 2 000 mg/kg bw, but treated animals showed acidosis, and some exhibited semi-coma and ophthalmic changes. Human data, however, indicate acute oral toxicity and ophthalmic changes at comparatively lower doses of 300 - 1 000 mg/kg bw.

A No-Observed-Adverse-Effect-Concentration (NOAEC) of 0.013 mg/L (13 mg/m³) is used for this risk assessment. This NOAEC is derived from a chronic inhalation study in monkeys, in which degenerative effects in the brain and slight damage to the optic and peripheral nerves were noted at 0.13 mg/L and above. Changes in peroneal nerves were also noted in higher dosed animals, indicating damage to peripheral nerves. An oral No Observed Adverse Effect Level (NOAEL) of 500 mg/kg bw/day was also established in rats in a 90-day oral study based on increased liver enzymes (enzymes not specified) and decreased absolute

brain weights at the highest dose. This value is not used in this risk assessment because acute oral data indicate that humans are more sensitive to methanol toxicity than rodents.

Information on repeated dose toxicity by the dermal route is not available. Methanol was not genotoxic or carcinogenic. Reproductive and developmental toxicity studies did not show any significant effects of relevance to humans.

33.3 Human exposure assessment

33.3.1 Worker exposure

Exposure of workers to methanol is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of volatilised chemical or its aerosols during operations. Exposure may also occur from contact with produced water containing residual methanol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.166) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the drilling and hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.166 Internal doses resulting from methanol exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	1.44x10 ⁻³	4.11x10 ⁻⁴	1.85x10 ⁻³
Mixing/blending of hydraulic fracturing chemicals	0.060	0.017	0.077
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

33.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised methanol to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to methanol via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses associated with drilling were derived for adults (Table D.167) and children (

Table D.168) as well as separate internal doses associated with hydraulic fracturing for adults (

Table D.169) and children (

Table D.170).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.167 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.080	N/A	0.080
Bathing in contaminated surface water	Negligible*	4.76 x 10 ⁻⁵	4.76 x 10 ⁻⁵
Swimming in contaminated surface water	5.95 x 10 ⁻⁶	4.76 x 10 ⁻⁵	5.35 x 10 ⁻⁵
Combined exposure from bulk spill – surface water use			0.08
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a)

Table D.168 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	0.280	N/A	0.280
Bathing in contaminated surface water	Negligible*	8.26 x 10 ⁻⁵	8.26 x 10 ⁻⁵
Swimming in contaminated surface water	8.32 x 10 ⁻⁵	8.82 x 10 ⁻⁵	1.71 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			0.281

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a)

Table D.169 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻³	1.98 x 10 ⁻³
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻³	2.23 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.343
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from subsurface leak – groundwater/surface water use Drinking, bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.170 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻³	3.44 x 10 ⁻³
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻³	7.15 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.697
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking, bathing in contaminated groundwater plus swimming in contaminated surface water			
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; *E_{derm}* – Internal dose from dermal exposure; *E_{total}* – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017c). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

33.4 Human health risk characterisation

33.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

33.4.2 Occupational health risks

33.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site (100 g/L, 10%) will result in adverse health effects such as dermal and inhalational toxicity and respiratory tract irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling and hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

33.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects were histopathological changes in the nervous system and fibrosis in kidneys and lungs in monkeys repeatedly exposed to methanol by the inhalation route. The NOAEC established for this effect in a chronic study was 0.013 mg/L (13 mg/m³). Assuming 100% inhalation absorption, an average body weight of monkey of 8 kg, and a respiratory rate of 5.4 m³/day of air (Derelanko 2000), this represents an absorbed dose of:

$$\frac{13 \text{ mg/m}^3 \times 5.4 \text{ m}^3/\text{day} \times 21 \text{ h}}{8 \text{ kg} \times 24 \text{ h}} = 7.7 \text{ mg/kg bw/day} \quad [\text{Equation D.7}]$$

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEC for this effect with exposures estimated for different occupational activities (Table D.171).

Table D.171 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	4160
Mixing/blending of hydraulic fracturing chemicals	100
Cleaning and maintenance (drilling)	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds and produced water are not calculated due to negligible human exposures (Table D.166).

Based on uncertainty factors derived for this risk characterisation, and the conservative assumptions within the exposure modelling, the MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during certain hydraulic fracturing operations (combined exposures from mixing / blending and cleaning and maintenance). The MOEs also indicate that the chemical is of low concern for workers from repeated exposures during drilling operations.

33.4.3 Public health risks

33.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

33.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and the NOAEC established for this effect, MOEs were calculated for adults and children for various exposure scenarios during drilling (Table D.172) and hydraulic fracturing (Table D.173).

Table D.172 Margins of Exposure calculated for different public exposure scenarios (Drilling)

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	96	27

Table D.173 Margins of Exposure calculated for different public exposure scenarios (Hydraulic fracturing)

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2	0.7
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (

Table D.169 and

Table D.170).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill (for drilling as well as hydraulic fracturing operations) and for children exposed to contaminated groundwater/surface water from a long-term subsurface leak from a storage pond. It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks.

A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

33.4.4 Conclusions

33.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for dermal and inhalational toxicity and respiratory tract irritation.

Exposure to chemical via drilling and hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated combined exposures via mixing / blending and cleaning and maintenance for hydraulic fracturing. Inhalation of chemical vapours may affect the nervous system. For drilling operations, the chemical as delivered to operational sites is of low concern for workers from repeated exposures.

33.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs are suggestive of a potential concern for adults and children in the event of an accidental transport spill (for both drilling and hydraulic fracturing operations) and for children from exposure to contaminated groundwater/surface water from a leaking storage pond. However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

33.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

33.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

33.5.2 Control measures available to minimise risks to the public

33.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

33.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

33.5.2.3 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

33.6 References

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D34 2-Propanol

CAS RN	CAS Name
67-63-0	2-Propanol

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

34.1 Chemical use and concentration

The document from here on refers to 2-Propanol (CAS RN 67-63-0) as 'isopropanol', one of the synonyms of the chemical.

The chemical is used as a component of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. The chemical's function is not specified in drilling formulations. The chemical's function in hydraulic fracturing formulations is as a surfactant.

Prior to incorporation into the final drilling and hydraulic fracturing fluids, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 300 g/L (30%) for drilling and up to 10 g/L (1%) for hydraulic fracturing. After incorporation, it is present in drilling fluids at a CBI concentration. The concentration of the chemical in hydraulic fracturing fluids after incorporation is assumed to be a default value of 1% in the absence of industry data.

34.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the Organisation for Economic Co-operation and Development (OECD 2002), International Program on Chemical Safety (IPCS 1990a, 1990b), European Food Safety Agency (EFSA 2005), and Kapp et al. (1993).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Isopropanol has low acute oral, dermal and inhalation toxicity, is not a skin irritant, and is an eye and respiratory irritant. The chemical is not a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect-Concentration (NOAEC) for risk assessment is 255 mg/kg bw/day based on kidney effects at the Lowest-Observed-Adverse-Effect-Concentration (LOAEC) of 1 275 mg/kg bw/day.

The chemical is not genotoxic or a carcinogen based on available data. Developmental toxicity occurred only at maternally toxic doses.

34.3 Human exposure assessment

34.3.1 Worker exposure

Exposure of workers to isopropanol is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual isopropanol.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.174) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling and hydraulic fracturing processes, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.174 Internal doses resulting from chemical exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.060	0.032	0.092
Mixing/blending of hydraulic fracturing chemicals	0.180	0.096	0.276
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	0.003	3.09 x 10 ⁻⁴	0.003
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Combined exposure Mixing/blending and cleaning and			0.280

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
maintenance (hydraulic fracturing)			
Drilling muds and produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

34.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air may be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.175) and children (

Table D.176).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.175 Internal doses for ADULTS associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (isopropanol in drilling product)			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻³	1.98 x 10 ⁻³
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻³	2.23 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.343
Accidental bulk spill during transport and surface runoff (isopropanol in hydraulic fracturing product)			
Drinking contaminated surface water	3.643	N/A	3.643
Bathing in contaminated surface water	Negligible*	2.16 x 10 ⁻³	2.16 x 10 ⁻³
Swimming in contaminated surface water	2.70 x 10 ⁻⁴	2.16 x 10 ⁻³	2.43 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.647
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond (isopropanol in hydraulic fracturing product)			
Drinking contaminated groundwater	0.098	N/A	0.098
Bathing in contaminated groundwater	Negligible*	5.43 x 10 ⁻⁵	5.43 x 10 ⁻⁵
Drinking contaminated surface water	1.78 x 10 ⁻⁵	N/A	1.78 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	9.87 x 10 ⁻⁹	9.87 x 10 ⁻⁹
Swimming in contaminated surface water	1.32 x 10 ⁻⁹	1.05 x 10 ⁻⁸	1.19 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.098

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water			1.78 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017c). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.176 Internal doses for CHILDREN associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (isopropanol in drilling product)			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻³	3.44 x 10 ⁻³
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻³	7.15 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.697
Accidental bulk spill during transport and surface runoff (isopropanol in hydraulic fracturing product)			
Drinking contaminated surface water	12.750	N/A	12.750
Bathing in contaminated surface water	Negligible*	3.75 x 10 ⁻³	3.75 x 10 ⁻³
Swimming in contaminated surface water	3.78 x 10 ⁻³	4.01 x 10 ⁻³	7.80 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			12.762
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond (isopropanol in hydraulic fracturing product)			
Drinking contaminated groundwater	0.342	N/A	0.342

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated groundwater	Negligible*	1.01 x 10 ⁻⁴	1.01 x 10 ⁻⁴
Drinking contaminated surface water	6.22 x 10 ⁻⁵	N/A	6.22 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.83 x 10 ⁻⁸	1.83 x 10 ⁻⁸
Swimming in contaminated surface water	1.85 x 10 ⁻⁸	1.96 x 10 ⁻⁸	3.80 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.342
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			6.22 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

34.4 Human health risk characterisation

34.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

34.4.2 Occupational health risks

34.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as eye irritation, irritation of the mucous membranes and central nervous system depression from isopropanol vapours. Given the concentration of the chemical in drilling products as delivered to operational sites (300 g/L or 30%), the chemical in this form is of potential concern regarding these effects in workers involved in drilling activities. Given the lower concentration of the chemical in hydraulic fracturing products (1%), the chemical in this form is of low concern regarding these effects in workers involved in hydraulic fracturing activities.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these

fluids will vary depending on work practices. However, given the low concentration in drilling fluids and assumed concentration in hydraulic fracturing fluids (10 g/L, 1%), exposure to the chemical via these fluids is of low concern for workers.

34.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is kidney toxicity. The NOAEC established for this effect is 255 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEC for this effect with exposures estimated for different occupational activities and combined activities (Table D.177).

Table D.177 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	2770
Cleaning and maintenance (drilling)	n.d.
Mixing/blending of hydraulic fracturing chemicals	926
Cleaning and maintenance (hydraulic fracturing)	7.80 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	912

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.174).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

34.4.3 Public health risks

34.4.3.1 Acute health risks

Given industrial use of isopropanol for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

34.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect of kidney toxicity and the NOAEC established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.178).

Table D.178 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff (isopropanol in drilling product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	76	22
Accidental bulk spill during transport and surface runoff (isopropanol in hydraulic fracturing product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	70	20
Long-term subsurface leak from flowback and / or produced water storage pond (isopropanol in hydraulic fracturing product)		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	2606	745
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	1.43×10^7	4.10×10^6

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.175 and

Table D.176).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern (kidney effects) for adults and children from repeated exposures based on the modelled exposure scenarios involving accidental bulk spills during transport for drilling and hydraulic fracturing.

These scenarios assume public contact with contaminated water. However, isopropanol has a low odour threshold in humans (geometric mean of 19 ppm (0.0019%)) as indicated by the American Industrial Hygiene Association (1989). This decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for human exposures would be reduced.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing

chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

34.4.4 Conclusions

34.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for eye irritation, irritation of the mucous membranes and central nervous system depression from isopropanol vapours when used in drilling products.

Exposure to the chemical via drilling and hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

34.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggest a potential concern for adults and children based on certain modelled exposure scenarios (bulk transport spill). However, isopropanol has a low odour threshold in humans which decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for human exposures would be reduced.

These public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

34.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

34.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

34.5.2 Control measures available to minimise risks to the public

34.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

34.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

34.6 References

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D35 Sulfuric acid, mono-C6-C10-alkyl esters, ammonium salts

CAS RN	CAS Name
68187-17-7	Sulfuric acid, mono-C6-C10-alkyl esters, ammonium salts

35.1 Chemical use and concentration

The document from here on refers to Sulfuric acid, mono-C6-C10-alkyl esters, ammonium salts (CAS RN 68187-17-7) as 'alkyl sulphates C6-C10', one of the synonyms of the chemical.

Alkyl sulphates C6-C10 is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction and comprises a range of carbon chain lengths. The substance is used as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is as a surfactant.

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid. In the absence of reported information on the concentrations of the substance, default concentrations of 300 g/L (30%) as transported and 0.85 g/L (0.085%) in the hydraulic fracturing fluid are assumed.

35.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Toxicology information on alkyl sulphates C6-C10 is not available. Toxicological information is available for alkyl sulphates (AS) with carbon chain lengths ranging from C8 to C18, sodium or ammonium salts (AS C8-C18) (HERA 2002). The chemical structures of the two groups of alkyl sulphates (AS C6-C10 and AS C8-C18) are similar, and compounds with carbon chain lengths of 8 to 10 carbons (AS C8-C10) are common to both groups of AS. Therefore, the available toxicological information on AS C8-C18 was used for reading across for AS C₆-C₁₀ toxicity, with preference for data on C₈ to C₁₂ chain lengths. Toxicity information was sourced primarily from the Human and Environmental Risk Assessment (HERA 2002) and from the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report (OECD 2007).

Available studies indicate that alkyl sulphates have moderate acute oral toxicity and low acute dermal toxicity. AS are considered to cause skin irritation and severe eye irritation, but are not regarded as skin sensitisers.

In repeat dose toxicity studies of AS with chain-lengths of at least 12 carbons, the liver appears to be the primary target organ, with increases in liver weight, cellular enlargement, and elevated levels of liver enzymes observed consistently. An oral No-Observed-Adverse-Effect Level (NOAEL) for repeat dose toxicity was established from a 90-day rat feeding

study on AS C12 sodium salt at 230 mg/kg bw/day. This NOAEL is used in this human health risk assessment.

Genotoxicity testing *in vitro* and *in vivo* did not suggest that AS of at least C12 chain length possess genotoxic potential. Carcinogenicity studies for AS are not available. Short- or long-term oral studies for AS did not report any evidence of carcinogenicity.

Available studies do not show evidence of fertility or developmental toxic effects in the absence of maternal toxicity for AS of at least C12 carbon chain length.

35.3 Human exposure assessment

35.3.1 Worker exposure

Exposure of workers to the hydraulic fracturing substance is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of the aerosolised substance during operations. Exposure may also occur from contact with produced water containing the residual fracturing substance.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total human (internal) dose (Table D.179) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further details on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, are available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.179 Internal doses resulting from alkyl sulphates C6-C10 exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.002	0.036	0.038
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	1.02x10 ⁻⁴	4.13x10 ⁻⁴	5.15x10 ⁻⁴
Combined exposure Mixing/blending and cleaning and			0.039

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
maintenance (hydraulic fracturing)			
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} – Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

35.3.2 Public exposure

The public may be exposed to alkyl sulphates C6-C10 via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised alkyl sulphates C6-C10 to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Exposures of the public to alkyl sulphates C6-C10 via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.180) and children (Table D.181).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.180 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	5.95 x 10 ⁻⁵	5.95 x 10 ⁻⁵
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	5.95 x 10 ⁻⁵	8.03 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			10.018
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.346	N/A	0.346
Bathing in contaminated groundwater	Negligible*	1.92 x 10 ⁻⁶	1.92 x 10 ⁻⁶
Drinking contaminated surface water	6.29 x 10 ⁻⁵	N/A	6.29 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	3.49 x 10 ⁻¹⁰	3.49 x 10 ⁻¹⁰
Swimming in contaminated surface water	4.67 x 10 ⁻⁹	3.73 x 10 ⁻¹⁰	5.04 x 10 ⁻⁹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.346
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			6.29 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water scenarios (see NICNAS 2017a).

Table D.181 Internal doses for CHILDREN associated with hydraulic fracturing public exposure

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.06	N/A	35.06
Bathing in contaminated surface water	Negligible*	1.03 x10 ⁻⁴	1.03 x10 ⁻⁴
Swimming in contaminated surface water	1.04 x10 ⁻²	1.10x10 ⁻⁴	1.05 x10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			35.070
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.212	N/A	1.212
Bathing in contaminated groundwater	Negligible*	3.57 x10 ⁻⁶	3.57 x10 ⁻⁶
Drinking contaminated surface water	2.20 x10 ⁻⁴	N/A	2.20 x10 ⁻⁴
Bathing in contaminated surface water	Negligible*	6.48 x10 ⁻¹⁰	6.48 x10 ⁻¹⁰
Swimming in contaminated surface water	6.53 x10 ⁻⁸	6.93 x10 ⁻¹⁰	6.60 x10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.212
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.20 x10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

35.4 Human health risk characterisation

35.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

35.4.2 Occupational health risks

35.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the substance as delivered to the site (assumed concentration of 300 g/L, 30%) will result in adverse health effects such as skin and eye irritation.

Acute, inadvertent exposures to the alkyl sulphates C6-C10 as delivered to operational sites are most likely during manual handling of the substance (if required) and during manipulation of equipment containing the residual substance during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the alkyl sulphates C6-C10 in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.85 g/L, 0.085%), exposure to the substance via these fluids is of low concern for workers.

35.4.2.2 Long-term health risks

From the hazard characterisation, the liver appears to be the primary target organ, with increases in liver weight, cellular enlargement, and elevated levels of liver enzymes observed consistently. The NOAEL established for these effects in a 90-day study was 230 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.182).

Table D.182 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	6 010
Cleaning and maintenance (hydraulic fracturing)	4.46 x 10 ⁵
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	5 930

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.179).

Based on uncertainty factors derived for this risk characterisation, and the assumptions within the exposure modelling, these MOEs indicate that the substance is of low concern for workers during operations.

35.4.3 Public health risks

35.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

35.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios during hydraulic fracturing (Table D.183).

Table D.183 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	23	7
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	664	190
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	3.66 x10 ⁶	1.04 x10 ⁶

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.180 and Table D.181).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children based on the modelled exposure scenario of a bulk transport spill.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular

chemical would require more information to enable refined exposure estimates or environmental monitoring data.

35.4.4 Conclusions

35.4.4.1 Occupational health risks

The concentrated form of alkyl sulphates C6-C10 as delivered to operational sites is of potential concern for workers during operations based on the potential for skin and eye irritation.

Calculated MOEs indicate that the substance as delivered to operational sites is of low concern for workers from repeated exposures during operations. The substance is a component of hydraulic fracturing fluids. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.85 g/L, 0.085%), exposure to the substance via these fluids is of low concern for workers.

35.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs suggest a potential concern for adults and children based on conservative Tier 1 exposure modelling of a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

35.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

35.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

35.5.2 Control measures available to minimise risks to the public

35.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

35.6 References

- HERA (2002) Human and Environmental Risk Assessment (HERA) on ingredients of household cleaning products (Alcohol Sulphates). January 2002. Accessed in February 2014 at: <http://www.heraproject.com/RiskAssessment.cfm?SUBID=3>.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2007) Screening Information Data Set (SIDS) Initial Assessment Profile for SIAM 25 for alkyl sulfates, alkane sulfonates and α -olefin sulfonates.

D36 Alcohols C₆₋₁₂, ethoxylated ethanol

CAS RN	CAS Name
68439-45-2	Alcohols C ₆₋₁₂ , ethoxylated ethanol

36.1 Chemical use and concentration

The document from here on refers to Alcohols C₆₋₁₂, ethoxylated ethanol (CAS RN 68439-45-2) as 'AE C₆₋₁₂', one of the synonyms of the substance.

AE C₆₋₁₂ is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction and comprises a range of carbon chain lengths and ethoxylated units. The substance is used as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is as a surfactant.

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid. In the absence of reported information on the concentrations of the substance, default concentrations of 300 g/L (30%) as transported and 0.85 g/L (0.085%) in the hydraulic fracturing fluid are assumed.

36.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Very little toxicological information is available on AE C₆₋₁₂. Toxicological information is available for a number of alcohol ethoxylate classes with carbon chain length distribution ranging from C₈ to C₁₈. Given that the chemical structures of the two groups of alcohol ethoxylates (AE C₆₋₁₂ and AE C₈₋₁₈) are very similar and the compounds with carbon chain lengths of 8-12 carbons (AE C₈₋₁₂) are common to both groups, the available toxicological information on alcohol ethoxylates that collectively covers the C8-C18 range and a similar number of ethoxylated units was used to read-across for AE C₆₋₁₂ toxicity. Toxicity information was sourced primarily from the Human and Environmental Risk Assessment report (HERA 2009).

AE C₆₋₁₂ is considered to have low to moderate acute oral and low acute dermal toxicity. Based on studies on closely related compounds, AE C₆₋₁₂ is expected to be a skin irritant and severe eye irritant but not a skin sensitiser.

Repeat dose oral studies indicate effects on organ weights and liver hypertrophy. An oral No-Observed-Adverse-Effect Level (NOAEL) of 50 mg/kg bw/day for systemic toxicity was determined in a 90-day study based on reduced mean body weights, increased liver and spleen weights, high urea, chloride and cholesterol and increased leucocytes and lymphocytes at the next higher dose. This NOAEL is used in this human health risk assessment.

Alcohol ethoxylates are not genotoxic or carcinogenic. Reproductive and developmental studies with a range of alcohol ethoxylates indicate no adverse effects on these parameters.

36.3 Human exposure assessment

36.3.1 Worker exposure

Exposure of workers to AE C₆₋₁₂ is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of the aerosolised substance during operations. Exposure to AE C₆₋₁₂ could occur by dermal route and through emission of the aerosolised substance by the inhalation route during manual handling. Exposure may also occur from contact with produced water containing the residual fracturing chemical.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.184) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.184 Internal doses resulting from AE C₆₋₁₂ exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.018	0.081	0.100
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.001	9.29x10 ⁻⁴	1.95x10 ⁻³
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.102
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

36.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to AE C₆₋₁₂ from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised AE C₆₋₁₂ to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for AE C₆₋₁₂ levels in ambient air. Exposures of the public to the substance via ambient air are also difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public health risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.185) and children (

Table D.186).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.185 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	5.95 x 10 ⁻⁴	5.95 x 10 ⁻⁴
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	5.95 x 10 ⁻⁴	1.34 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			10.019
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.346	N/A	0.346
Bathing in contaminated groundwater	Negligible*	1.92 x 10 ⁻⁵	1.92 x 10 ⁻⁵
Drinking contaminated surface water	6.29 x 10 ⁻⁵	N/A	6.29 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	3.49 x 10 ⁻⁹	3.49 x 10 ⁻⁹
Swimming in contaminated surface water	4.67 x 10 ⁻⁹	3.73 x 10 ⁻⁹	8.40 x 10 ⁻⁹
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.346
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			6.29 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.186 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.06	N/A	35.06
Bathing in contaminated surface water	Negligible*	1.03 x 10 ⁻³	1.03 x 10 ⁻³
Swimming in contaminated surface water	1.04 x 10 ⁻²	1.10 x 10 ⁻³	1.15 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			35.072
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.212	N/A	1.212
Bathing in contaminated groundwater	Negligible*	3.57 x 10 ⁻⁵	3.57 x 10 ⁻⁵
Drinking contaminated surface water	2.20 x 10 ⁻⁴	N/A	2.20 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	6.48 x 10 ⁻⁹	6.48 x 10 ⁻⁹
Swimming in contaminated surface water	6.53 x 10 ⁻⁸	6.93 x 10 ⁻⁹	7.23 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.212
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.20 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

36.4 Human health risk characterisation

36.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

36.4.2 Occupational health risks

36.4.2.1 Acute health risks

Health effects information indicates that acute exposure to AE C₆₋₁₂ as delivered to the site (assumed concentration of 300 g/L, 30%) will result in adverse health effects such as skin and eye irritation.

Acute, inadvertent exposures to the substance as delivered to operational sites are most likely during manual handling of the chemicals (if required) and during manipulation of equipment containing the residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.85 g/L, 0.085%), exposure to AE C₆₋₁₂ via these fluids is of low concern for workers.

36.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects were reduced mean body weights, increased liver and spleen weights, high urea, chloride and cholesterol and increased leucocytes and lymphocytes. The NOAEL established for these effects in a chronic study was 50 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities (Table D.187).

Table D.187 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemical	500
Cleaning and maintenance (hydraulic fracturing)	25 660
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	490

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.184).

Based on uncertainty factors derived for this risk characterisation, and the assumptions within the exposure modelling, these MOEs indicate that AE C₆₋₁₂ as delivered to operational sites is of low concern for workers during mixing / blending fluids for hydraulic fracturing.

Given the low concentration of the substance in drilling and hydraulic fracturing fluids repeated exposure to AE C₆₋₁₂ via these fluids is of low concern for workers.

36.4.3 Public health risks

36.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with AE C₆₋₁₂ as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

36.4.3.2 Long-term health risks

The public is most likely to come into contact with AE C₁₂₋₁₆ via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios during hydraulic fracturing (Table D.188).

Table D.188 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	5	1
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	144	41
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	7.95×10^5	2.27×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.185 and

Table D.186).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill, and for children for repeated exposures to contaminated groundwater/surface water from a leaking storage pond.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

36.4.4 Conclusions

36.4.5 Occupational health risks

The concentrated form of AE C12-C16 as delivered to operational sites is of potential concern for workers during operations based on its skin and eye irritation potential.

Calculated MOEs indicate that the substance is of low concern for workers from repeated exposures during operations.

36.4.6 Public health risks

The public is unlikely to come into contact with AE C12-C16 as delivered to operational sites, and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggest a potential concern for adults in the event of an accidental spill and for children for the modelled exposure scenario of a storage pond leak and exposure to groundwater/surface water.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of the risk would require more information to enable refined exposure estimates or environmental monitoring data.

36.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

36.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

36.5.2 Control measures available to minimise risks to the public

36.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

36.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

36.6 References

NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

HERA (2009) Human and Environmental Risk Assessment (HERA) on ingredients of household cleaning products (alcohol ethoxylates). Version 2, September 2009. Accessed in January 2014 at: http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf.

D37 Terpenes and terpenoids, sweet orange oil

CAS RN	CAS Name
68647-72-3	Terpenes and terpenoids, sweet orange oil

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

37.1 Chemical use and concentration

This document from here on refers to Terpenes and terpenoids, sweet orange oil (CAS RN 68647-72-3) as 'sweet orange oil terpenes', one of the synonyms of the chemical. Sweet orange oil is a substance of unknown or variable composition, complex reaction products or biological materials (UVCB) having biological origins. It is composed of approximately 97.1% monoterpene hydrocarbons, at least 91% of which consists of *d*-limonene (US EPA 2009).

The substance is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a surfactant.

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 300 g/L (30%). After incorporation, it is present in hydraulic fracturing fluid at a concentration which is confidential business information (CBI).

37.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

Information on health hazard was obtained predominantly from US EPA (2009) and NICNAS (2002). Data gaps for the substance are read-across from data available for *d*-limonene.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sweet orange oil terpenes has low acute oral and dermal toxicity based on reading across the data available for sweet orange oil and *d*-limonene. Based on reading across the data available for *d*-limonene, the substance is a skin irritant and a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment is 600 mg/kg bw/day based on decreased bodyweight at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 1 200 mg/kg bw/day in a study on *d*-limonene. This NOAEL will be applied to sweet orange oil terpenes.

Sweet orange oil terpenes is neither genotoxic nor a developmental toxicant based on data available for sweet orange oil and *d*-limonene. The substance is not carcinogenic based on reading across the data available for *d*-limonene.

37.3 Human exposure assessment

37.3.1 Worker exposure

Exposure of workers to sweet orange oil terpenes is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/ aerosols during operations. Exposure may also occur from contact with produced water containing residual substance.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered, as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities of mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.189) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.189 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.180	0.022	0.202
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

37.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the substance via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air may be low compared to exposures via water, noting the substance is somewhat volatile. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.190) and children (Table D.191).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.190 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	1.873	N/A	1.873
Bathing in contaminated surface water	Negligible*	1.11 x 10 ⁻³	1.11 x 10 ⁻³
Swimming in contaminated surface water	1.39 x 10 ⁻⁴	1.11 x 10 ⁻³	1.25 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			1.876
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.191 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	6.556	N/A	6.556
Bathing in contaminated surface water	Negligible*	1.93 x 10 ⁻³	1.93 x 10 ⁻³
Swimming in contaminated surface water	1.95 x 10 ⁻³	2.06 x 10 ⁻³	4.01 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			6.562
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

37.4 Human health risk characterisation

37.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children.

Consequently, in the risk characterisation, an MOE of less than 100 is considered of concern.

37.4.2 Occupational health risks

37.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the substance as delivered to operational sites (300 g/L, 30%) will result in adverse health effects such as skin irritation and skin sensitisation.

Acute, inadvertent exposures to the substance as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual substance during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the substance via these fluids is of low concern for workers.

37.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the substance is decreased bodyweight. The NOAEL established for this effect is 600 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.192).

Table D.192 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	2.97 x 10 ³
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.189).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

37.4.3 Public health risks

37.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

37.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.193).

Table D.193 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	320	91
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.190 and

Table D.191).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for children from repeated exposures from environmental contamination from a bulk transport spill. For other exposure scenarios, MOEs based on conservative exposure modelling indicate a low concern for adults and children from repeated exposures.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

37.4.4 Conclusions

37.4.4.1 Occupational health risks

The substance as delivered to operational sites is of potential concern for workers during operations based on the potential for skin irritation and skin sensitisation.

Calculated MOEs indicate that the substance is of low concern for workers from repeated exposures during operations.

37.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on Tier 1 exposure modelling suggest a potential concern for children for the modelled exposure scenario of a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

37.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

37.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

37.5.2 Control measures available to minimise risks to the public

37.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

37.6 References

NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

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D38 Methanaminium, N, N, N-trimethyl-, chloride (1:1)

CAS RN	CAS Name
75-57-0	Methanaminium, N, N, N-trimethyl-, chloride (1:1)

38.1 Chemical use and concentration

This document from here on refers to methanaminium, N, N, N-trimethyl-, chloride (1:1) (CAS RN 75-57-0) as 'tetramethylammonium chloride', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is clay control.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 612 g/L (61.2%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 1.27 g/L (0.127%).

38.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazard was obtained predominantly from the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH 2013) dossier and the Organisation for Economic Co-operation and Development (OECD 2007). Data from tetramethylammonium hydroxide (CAS RN 75-59-2) are used to read-across for certain endpoints of tetramethylammonium chloride.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Tetramethylammonium chloride has moderate to high acute oral toxicity, moderate acute dermal toxicity, is irritating to the skin, and is not an eye irritant or a skin sensitiser.

A No-Observed-Adverse-Effect Level (NOAEL) was not established since no adverse effects were observed for the analogue chemical tetramethylammonium hydroxide at a maximum dose of 20 mg/kg bw/day from a 28-day rat study. An adjustment factor of three is applied to the highest no-effect dose as the study was of inadequate duration. Consequently, based on the absence of adverse effects observed in this study of tetramethylammonium hydroxide, for the purposes of quantifying the health risk, the highest adjusted dose tested in the study (6.7 mg/kg bw/day) is used in this risk assessment of tetramethylammonium chloride.

The chemical is not genotoxic or carcinogenic. Tetramethylammonium chloride is not a reproductive toxicant based on read-across data available for tetramethylammonium hydroxide.

38.3 Human exposure assessment

38.3.1 Worker exposure

Exposure of workers to tetramethylammonium chloride is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual tetramethylammonium chloride.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.194) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.194 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.367	0.016	0.383
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.015	1.33 x 10 ⁻⁴	0.015
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.398
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

38.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.195) and children (Table D.196).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.195 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	20.435	N/A	20.435
Bathing in contaminated surface water	Negligible*	1.21 x 10 ⁻²	1.21 x 10 ⁻²
Swimming in contaminated surface water	1.52 x 10 ⁻³	1.21 x 10 ⁻²	1.36 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			20.460
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.517	N/A	0.517
Bathing in contaminated groundwater	Negligible*	2.87 x 10 ⁻⁴	2.87 x 10 ⁻⁴
Drinking contaminated surface water	9.40 x 10 ⁻⁵	N/A	9.40 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	5.22 x 10 ⁻⁸	5.22 x 10 ⁻⁸
Swimming in contaminated surface water	6.97 x 10 ⁻⁹	5.58 x 10 ⁻⁸	6.28 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.518
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			9.41 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.196 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	71.521	N/A	71.521
Bathing in contaminated surface water	Negligible*	2.11 x 10 ⁻²	2.11 x 10 ⁻²
Swimming in contaminated surface water	2.12 x 10 ⁻²	2.25 x 10 ⁻²	4.37 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			71.586
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.811	N/A	1.811
Bathing in contaminated groundwater	Negligible*	5.33 x 10 ⁻⁴	5.33 x 10 ⁻⁴
Drinking contaminated surface water	3.29 x 10 ⁻⁴	N/A	3.29 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	9.69 x 10 ⁻⁸	9.69 x 10 ⁻⁸
Swimming in contaminated surface water	9.76 x 10 ⁻⁸	1.03 x 10 ⁻⁷	2.01 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.812
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			3.29 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

38.4 Human health risk characterisation

38.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for the affected population

e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

38.4.2 Occupational health risks

38.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to site (612 g/L, 61.2%) will result in adverse health effects such as acute dermal toxicity and skin irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (1.27 g/L, 0.127%), exposure to the chemical via these fluids is of low concern for workers.

38.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at the highest adjusted dose tested of 6.7 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest adjusted no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.197).

Table D.197 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	18
Cleaning and maintenance (hydraulic fracturing)	436
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	17

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.194). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects, and the MOEs for mixing / blending and combined exposures during mixing / blending and cleaning and maintenance a potential concern cannot be ruled out for workers from these modelled scenarios. The MOE > 100 for cleaning and maintenance indicates a low concern for workers engaged in these activities.

38.4.3 Public health risks

38.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

38.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Noting there are no adverse effects observed from repeated exposures to the chemical at the highest adjusted dose tested of 6.7 mg/kg bw/day, MOEs were calculated for adults and children for various exposure scenarios (Table D.198).

Table D.198 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	0.3	0.1
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	13	4
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	7.12×10^4	2.03×10^4

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.195 and Table D.196). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects, and the MOEs < 100 derived for repeated public exposures to contaminated water from a bulk transport spill or leaking storage pond (groundwater/surface water use), a potential concern cannot be ruled out for adults and children. In contrast, the MOEs > 100 for the modelled scenario of exposures only to surface water contaminated from a leaking storage pond indicate a low concern for repeated exposures for this scenario.

38.4.4 Conclusions

38.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for acute dermal toxicity and skin irritation.

For repeated exposures of workers to the chemical as delivered to site, based on the MOEs, a potential concern cannot be ruled out for workers.

38.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public, based on the calculated MOEs a potential concern cannot be ruled out for adults and children for scenarios involving a bulk transport spill and leaking storage pond. Calculated MOEs indicate a low concern for the public for the scenario of the leaking storage pond if repeated exposures are confined to surface water.

38.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

38.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

38.5.2 Control measures available to minimise risks to the public

For some exposure scenarios, it is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for adults and / or children from repeated exposure to the chemical from water contamination.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

38.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

38.5.2.2 Storage of flowback and / or produced water

For chemicals with potential concerns from contamination of shallow groundwater from a leaking storage pond, the following risk mitigation measures are available (NICNAS 2017b)

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

38.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD 2007) Screening Information Data Set (SIDS) Initial Assessment Report for SIAM22: tetramethylammonium hydroxide. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database. Accessed 19 September 2013 at http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=7112d373-b578-4221-b886-fc4b4023f7d1&idx=0

REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on tetramethylammonium chloride (CAS RN 75-57-0). European Union. Accessed 30 August 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D39 Hydrochloric acid

CAS RN	CAS Name
7647-01-0	Hydrochloric acid

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

39.1 Chemical use and concentration

Hydrochloric acid, which is chemically equivalent to a solution of hydrogen chloride gas in water, is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a pH controller.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a confidential business information (CBI) concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

39.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substances (NICNAS 2017c).

Information on hydrogen chloride/hydrochloric acid was sourced primarily from the Organisation for Economic Co-operation and Development (OECD 2005).

The information on health hazards was sourced primarily from the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report for hydrogen chloride (OECD 2005) and the International Agency for Research on Cancer monograph on hydrochloric acid (IARC 1992).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Following absorption, the chemical dissociates rapidly into hydrogen ions and chloride ions which are normal, regulated components of the human body. Chloride ions enter the body's electrolyte pool and are regulated by well described physiological processes. The hydrogen ions react with various buffering components in biological fluids to form water. Humans secrete hydrochloric acid into the stomach at high concentration and uptake is buffered by the simultaneous endogenous production of bicarbonate.

Hydrochloric acid has demonstrated acute oral toxicity, corrosive effects to the skin and eye, and irritant effects to the respiratory system. Hydrochloric acid is not a skin sensitiser based on the available studies.

Only limited information on the repeated oral toxicity of hydrochloric acid is available. However, as the component ions are normal constituents of the human body (particularly the stomach), only localised effects are expected. In rats, inhalation exposure to hydrogen chloride gas (50 ppm) for 90 days was associated with histopathological changes in the respiratory tract and decreased body weight gain. Based on the reduction in body weight

gain, the No-Observed-Adverse-Effect-Concentration (NOAEC) of 20 ppm (equivalent to 6.2 mg/kg bw/day) is used in this risk assessment for hydrochloric acid.

The acid is not genotoxic. No evidence of treatment related carcinogenicity was observed in animal studies performed by inhalation or dermal administration. In humans, no association between hydrogen chloride exposure and tumour incidence was observed.

No reliable studies were identified regarding specific toxicity to reproduction and development in animals after exposure to hydrogen chloride/hydrochloric acid. Because hydrogen and chloride ions are normal constituents in the body fluids, low concentrations of hydrochloric acid/hydrogen chloride would not be expected to cause adverse reproductive effects to animals. This conclusion is supported by the 90-day inhalation study where no effects on the gonads of rodents were observed.

39.3 Human exposure assessment

39.3.1 Worker exposure

Exposure of workers to hydrochloric acid is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical during operations. Exposure may also occur from contact with produced water containing residual hydrochloric acid.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.199) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.199 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} – Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

39.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised hydrochloric acid to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to hydrochloric acid via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.200) and children (Table D.201).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.200 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.201 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

39.4 Human health risk characterisation

39.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No other uncertainty factors are deemed necessary to account for the nature of adverse health

effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

39.4.2 Occupational health risks

39.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site will result in adverse health effects such as severe skin burns, eye damage and respiratory irritation.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

39.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is decreased body weight gain in a 90-day inhalation study where effects on the respiratory tract were also noted. The NOAEC established for the reduction in body weight gain is 20 ppm (6.2 mg/kg bw/day).

MOEs for the health effect from repeated occupational exposures are calculated by comparing the NOAEC for this effect with exposures estimated for different occupational activities and combined activities (Table D.202).

Table D.202 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.199).*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during mixing / blending operations and for combined exposure from mixing / blending and cleaning and maintenance.

However, as noted, the chemical dissociates rapidly into hydrogen ions and chloride ions which are normal, homeostatically regulated components of the human body. Therefore, inasmuch as these MOE calculations for health effects from repeated doses suggest a potential health concern, the calculations reflect secondary effects resulting from the local

effects associated with the acidic nature of the chemical and not systemic effects from the chemical itself in the body.

Therefore, overall, the chemical is of low concern for workers for systemic effects from repeated exposures.

39.4.3 Public health risks

39.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

39.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEC established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.203).

Table D.203 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak–groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak–surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.200 and Table D.201).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures in the event of a bulk transport spill and exposures to contaminated groundwater/surface water from a leaking storage pond. However, as noted, the chemical dissociates rapidly into hydrogen ions and chloride ions which are normal, regulated components of the human body. Therefore, in as much as these MOE calculations for health effects in the public from repeated doses suggest a potential

health concern, the calculations reflect secondary effects from the local effects associated with the acidic nature of the chemical and not actual systemic effects.

Therefore, overall, the chemical is of low concern for the public for systemic effects from repeated exposures.

Also, hydrochloric acid has a taste threshold in humans of 0.9 mM (36 mg/L) (Bowen 2006). The modelled PEC for an accidental bulk spill of hydrochloric acid is much higher than this taste threshold, meaning that individuals exposed to the chemical in contaminated water arising from a bulk spill would be able to detect the sour taste of the acid. Moreover, this PEC corresponds to a strongly acidic pH, meaning even a single immersion in this contaminated water would cause significant eye and skin irritation. Under these circumstances, individuals would therefore become aware of the contamination. This decreases the likelihood of a chemical contamination remaining undetected and so, in this instance, the potential for ongoing human exposure would be reduced.

Also, public health risks associated with exposures via a subsurface leak are also likely to be mitigated by the very dilute hydrochloric acid being neutralised by the slightly alkaline environment of the earth.

39.4.4 Conclusions

39.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for severe skin burns, eye damage and respiratory irritation.

The chemical as delivered to operational sites is of low concern for workers following repeated exposures during certain operations.

39.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures via environmental contamination, the chemical is of low concern for the public for all the modelled exposure scenarios.

Moreover, due to the high acidity expected of water contaminated after an accidental bulk spill, the eye and skin irritation and sour taste that is likely to occur following initial drinking will likely mitigate against repeat exposures. Also, public health risks associated with exposures via a subsurface leak are also likely to be mitigated by the very dilute hydrochloric acid being neutralised by the slightly alkaline environment of the earth.

39.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

39.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

39.5.2 Control measures available to minimise risks to the public

39.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

39.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

39.5.2.3 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017b).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.

- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

39.6 References

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D40 Hypochlorous acid, sodium salt

CAS RN	CAS Name
7681-52-9	Hypochlorous acid, sodium salt

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

40.1 Chemical use and concentration

The document from here on refers to hypochlorous acid, sodium salt (CAS RN 7681-52-9) as 'sodium hypochlorite', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a biocide or gel breaker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 300 g/L (30%). After incorporation, it is present in hydraulic fracturing fluid at confidential business information (CBI) concentration.

40.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substances (NICNAS 2017c).

Information on health hazards was sourced primarily from a toxicological profile of chlorine (ATSDR 2010) and a European Union Risk Assessment Report for the chemical (European Chemicals Bureau 2007).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sodium hypochlorite demonstrates low acute toxicity. It is corrosive to the skin, eyes and the gastrointestinal tract. Based on human and animal data, sodium hypochlorite concentrations over 5% are irritating to the skin and eye, while concentrations over 10% are corrosive. Aerosolised sodium hypochlorite is a respiratory irritant. The chemical is not a skin sensitiser.

No systemic effects in animals are associated with repeated exposure to sodium hypochlorite at the tested dose levels. The critical study is a two-year drinking water study in rats, where no adverse effects were seen at a top dose of 13.6-14.2 mg/kg bw/day. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk, the highest dose tested in the critical study (13.6 mg/kg bw/day) is used in this risk assessment.

Available data indicate that the chemical is not genotoxic. There is inadequate evidence for the carcinogenicity of sodium hypochlorite in animals, and it is not considered to cause fertility or developmental effects.

Overall, the main critical effect to human health of sodium hypochlorite is its corrosivity.

40.3 Human exposure assessment

40.3.1 Worker exposure

Exposure of workers to sodium hypochlorite is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical during operations. Exposure may also occur from contact with produced water containing residual sodium hypochlorite.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.204) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.204 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.180	0.119	0.299
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

40.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.205) and children (Table D.206).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.205 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	5.95 x 10 ⁻³	8.76 5.95 x

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
			10 ⁻³
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	5.95 x 10 ⁻³	6.69 x 10 ⁻³
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			10.030
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak- groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak- surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.206 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.06	N/A	35.06
Bathing in contaminated surface water	Negligible*	1.03 x 10 ⁻²	1.03 x 10 ⁻²
Swimming in contaminated surface water	1.04 x 10 ⁻²	1.10 x 10 ⁻²	2.14 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming			35.091

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
in contaminated surface water			
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; – not disclosed. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

40.4 Human health risk characterisation

40.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No other uncertainty factors are deemed necessary to account for the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

40.4.2 Occupational health risks

40.4.2.1 Acute health risks

Health effects information indicates that acute exposure to approximately 10% or more concentrated solutions of the chemical will result in adverse health effects such as severe burns to the skin and eyes. Given the concentration of the chemical as delivered to operational sites (300 g/L or 30%), the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

40.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 13.6 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.207).

Table D.207 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	46
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. –not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.204). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

In light of uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling toxicological studies that did not identify a dose of the chemical associated with adverse effects, and the MOEs a potential concern cannot be ruled out for workers from repeated exposures under the modelled scenarios.

40.4.3 Public health risks

40.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

40.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 13.6 mg/kg bw/day. Based on this

highest no-effect dose, the MOEs were calculated for adults and children for various exposure scenarios (Table D.208).

Table D.208 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	1.4	0.4
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.205 and Table D.206). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and toxicological studies that did not identify a dose of the chemical associated with adverse effects the MOEs for the leaking storage pond scenario (groundwater/surface water use and surface water use alone) indicate a low concern for repeated exposures for this exposure scenario. MOEs < 100 for the accidental bulk spill scenario indicate that a potential concern for repeated exposures for this modelled scenario cannot be ruled out.

Notwithstanding these MOEs, the concentration of the chemical in contaminated water arising from a bulk spill during transport is predicted to be less than the concentrations that would give rise to acute irritation effects. Also, any health risks arising from exposure to contaminated water via subsurface water are unlikely to eventuate considering the chemical fate of sodium hypochlorite. This is because the chemical, as an oxidising agent, will most likely be consumed by the reducing environment of the coal seam (The Colorado Department of Labor and Employment Division of Oil and Public Safety 2007) before it travels through groundwater to waters used or consumed by the public. At this point, the chemical will have converted to the more benign sodium chloride.

40.4.4 Conclusions

40.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for causing severe skin burns and eye damage.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate a potential concern for workers for repeated exposures during operations.

40.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from a leaking storage pond, calculated MOEs indicate a low concern for adults and children. MOEs for the bulk spill scenario indicate a potential concern for repeated exposures for this exposure scenario.

40.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

40.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

40.5.2 Control measures available to minimise risks to the public

40.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

40.5.2.2 Transport

For this chemical, risk estimates from conservative exposure modelling do not allow a definitive conclusion regarding the level of concern for the public from contamination of surface water from a transport spill.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

40.6 References

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D41 Hydrogen peroxide (H₂O₂)

CAS RN	CAS Name
7722-84-1	Hydrogen peroxide (H ₂ O ₂)

41.1 Chemical use and concentration

Hydrogen peroxide is noted on Australian industry websites as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its stated function within these fluids is in gel management.

No identity or concentration data were reported for hydrogen peroxide in the coal seam gas industry survey (NICNAS 2017b). A safety data sheet for 'frac gel breaker' product GBW-41L, typically used in hydraulic fracturing in New Zealand (ChemAlert 2007), lists hydrogen peroxide present at a concentration of 5-15%. Therefore, for the purposes of this risk assessment, the chemical is assumed to be transported, stored and handled within a liquid product at a concentration of 150 g/L (15%).

No data were provided in the industry survey for the final concentration of hydrogen peroxide in fracturing fluid prior to use. Instead, a concentration is estimated based on the following industry information for use of GBW-41L containing hydrogen peroxide (New Zealand Petroleum and Minerals 2012):

- hydrogen peroxide present in GBW-41L at a maximum of 15%.
- GBW-41L used in hydraulic fracturing fluid at 0.16%.

Based on the assumption that fracturing fluids of similar composition are used in Australia, for the purposes of this risk assessment it is estimated that the amount of hydrogen peroxide compared to the total volume of hydraulic fracturing fluids is 0.24 g/L (0.024%).

41.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on hydrogen peroxide was sourced primarily from the European scientific opinion on hydrogen peroxide in oral hygiene and tooth whitening products (Scientific Committee on Consumer Products \ 2007) and a European Union Risk Assessment Report for hydrogen peroxide (European Chemicals Bureau 2003).

Hydrogen peroxide demonstrates moderate acute toxicity by the oral and inhalation routes and low acute toxicity by the dermal route. The chemical is corrosive to the skin and eyes and is a respiratory irritant. Based on animal data, concentrations of greater than 35% are irritating to the skin, while a concentration of 50% is corrosive. Hydrogen peroxide is not a skin sensitiser.

Repeated oral exposures to the chemical produced localised inflammation of the gastric mucosa accompanied by erosion, ulceration and hyperplasia. Adverse systemic effects included decreased bodyweight gain, haematological changes and changes in blood and organ enzyme levels. The most appropriate No Observed Adverse Effect Level (NOAEL) for risk assessment of hydrogen peroxide, determined from a 100-day gavage study in rats, is

30 mg/kg bw/day based on systemic effects (decreased plasma catalase) at the Lowest Observed Adverse Effect Level (LOAEL) of 60 mg/kg bw/day.

While the chemical is genotoxic in a variety of *in vitro* test systems, available studies do not provide evidence of a significant mutagenicity under *in vivo* conditions. Although hydrogen peroxide has the potential to induce localised carcinomas in the duodenum of sensitive mice, regression after cessation of treatment and lack of an effect in another species suggest that the carcinogenicity of the chemical is not practically significant in humans.

Reliable data on reproductive and developmental toxicity are not available.

Overall, the main critical effect to human health is corrosivity.

41.3 Human exposure assessment

41.3.1 Worker exposure

Exposure of workers to hydrogen peroxide is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual hydrogen peroxide.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.209) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.209 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.090	0.003	0.093
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic	0.003	1.75 x 10 ⁻⁵	0.003

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
fracturing)			
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.096
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

41.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of

exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.210) and children (Table D.211).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.210 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	5.009	N/A	5.009
Bathing in contaminated surface water	Negligible*	2.97 x 10 ⁻³	2.97 x 10 ⁻³
Swimming in contaminated surface water	3.72 x 10 ⁻⁴	2.97 x 10 ⁻³	3.34 x 10 ⁻³
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			5.015
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.098	N/A	0.098
Bathing in contaminated groundwater	Negligible*	5.43 x 10 ⁻⁵	5.43 x 10 ⁻⁵
Drinking contaminated surface water	1.78 x 10 ⁻⁵	N/A	1.78 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	9.87 x 10 ⁻⁹	9.87 x 10 ⁻⁹
Swimming in contaminated surface water	1.32 x 10 ⁻⁹	1.05 x 10 ⁻⁸	1.19 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.098
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			1.78 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.211 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	17.53	N/A	17.53
Bathing in contaminated surface water	Negligible*	5.16 x 10 ⁻³	5.16 x 10 ⁻³
Swimming in contaminated surface water	5.20 x 10 ⁻³	5.52 x 10 ⁻³	1.07 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			17.546
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.342	N/A	0.342
Bathing in contaminated groundwater	Negligible*	1.01 x 10 ⁻⁴	1.01 x 10 ⁻⁴
Drinking contaminated surface water	6.22 x 10 ⁻⁵	N/A	6.22 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.83 x 10 ⁻⁸	1.83 x 10 ⁻⁸
Swimming in contaminated surface water	1.85 x 10 ⁻⁸	1.96 x 10 ⁻⁸	3.80 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.342
Combined exposure from subsurface leak-surface water use Drinking, and bathing and swimming in contaminated surface water			6.22 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

41.4 Human health risk characterisation

41.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

41.4.2 Occupational health risks

41.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the relatively concentrated solutions of the chemical will result in adverse health effects, such as harm by inhalation, serious burns to the skin and eye damage. Given the assumed concentration of the chemical as delivered to operational sites (150 g/L or 15%), the chemical in this form will result in the risk of serious eye damage and is therefore of potential concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.24 g/L or 0.024%), exposure to the chemical via these fluids is of low concern for workers.

41.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is reduced plasma catalase levels. The NOAEL established for this effect is 30 mg/kg bw/day.

MOEs for this health effect from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.212).

Table D.212 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	324
Cleaning and maintenance (hydraulic fracturing)	1.04 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	314

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.209).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

41.4.3 Public health risks

41.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

41.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.213).

Table D.213 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	6	2
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak– groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	307	88
Combined exposure from subsurface leak– surface water use Drinking, bathing and swimming in contaminated surface water	1.69×10^6	4.82×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.210 and Table D.211).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill and to children from repeated exposure to groundwater/ surface water contaminated from a leaking storage pond.

However, although these MOEs are suggestive of a potential concern for children for the scenario involving a subsurface leak from a flowback and / or produced water storage pond, health risks are likely to be mitigated for this scenario considering the chemical fate of hydrogen peroxide. This is because the chemical, as an oxidising agent, will most likely be consumed by the reducing environment of the coal seam (The Colorado Department of Labor and Employment Division of Oil and Public Safety 2007) before it travels through groundwater to waters used or consumed by the public. At this point, the chemical will have converted to water.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure

scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017b). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

41.4.4 Conclusions

41.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for serious damage to the eyes.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

41.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites, and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs suggest a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill and to children from repeated exposure to groundwater/ surface water contaminated from a leaking storage pond. However, health risks associated with leakage from a flowback/produced water storage pond will be likely mitigated by degradation of the chemical by the reducing environment of the coal seam prior to storage in the pond.

These public health risks were estimated using conservative exposure modelling (including not considering environmental fate) and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

41.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

41.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

41.5.2 Control measures available to minimise risks to the public

41.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

41.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

41.6 References

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D42 Peroxydisulfuric acid (((HO)S(O)₂)₂O₂), diammonium salt

CAS RN	CAS Name
7727-54-0	Peroxydisulfuric acid (((HO)S(O) ₂) ₂ O ₂), diammonium salt

42.1 Chemical use and concentration

The document from here on refers to Peroxydisulfuric acid (((HO)S(O)₂)₂O₂), diammonium salt (CAS RN 7727-54-0) as 'ammonium persulfate', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a gel breaker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 1 000 g/kg (100%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.452 g/L (0.045%).

42.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

As they are closely related chemicals, the adverse effects on human health of two persulfates, ammonium persulfate (CAS RN 7727-54-0) and sodium persulfate (CAS RN 7775-27-1), notified as used in the coal seam gas extraction process, were assessed together in a group hazard assessment (NICNAS 2017a). This was on the basis that the two substances are the ammonium and sodium salts of the same persulfate anion, which is an oxidising agent.

Information on ammonium persulfate was sourced primarily from the Organisation for Economic Co-operation and Development (OECD 2005) and the NICNAS Priority Existing Chemical Assessment Report No. 18 (NICNAS 2001).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Although ammonium persulfate is harmful by the oral route, this potential for acute toxicity is generally not demonstrated via the dermal or inhalation routes. The chemical is non-irritating to slightly irritating to the eyes and respiratory system, and it is not a skin irritant in animal studies. However, studies in humans indicate that it can cause irritation.

Ammonium persulfate is capable of inducing skin and respiratory sensitisation in animals and these are also the major chronic effects observed in humans. Mouse local lymph node assay results for ammonium persulfate suggest that the chemical is a moderate to strong sensitiser.

The most sensitive endpoint for ammonium persulfate is effects on the respiratory system, with a No-Observed-Adverse-Effect-Concentration (NOAEC) of 10.3 mg/m³ (equivalent to 2.1 mg/kg bw/day) in a 90-day inhalation study. Local effects, including respiratory tract

inflammation, increased lung weight and rales were observed in rats at the Lowest-Observed-Adverse-Effect-Concentration (LOAEC) of 25 mg/m³. A systemic effect observed at this concentration was decreased body weight, which may be a consequence of adverse local effects on the respiratory tract rather than as a direct action of the oxidising chemical. An older, 28-day repeat oral dose study provided a much larger NOAEL of 41 mg/kg bw/day, based on decreased relative adrenal weight at the top dose. However, as this study was not well documented and is also potentially confounded by local irritant effects arising from the oxidising chemical, the more conservative NOAEL of 2.1 mg/kg bw/day is used. In contrast, an oral dosing study is used to derive a NOAEL in the risk assessment of the closely related chemical, sodium persulfate (CAS RN 7775-27-1).

Ammonium persulfate is not genotoxic, and it does not cause tumour induction or promotion in a mouse skin model.

Repeated oral exposures to the chemical provided evidence that ammonium persulfate is not a reproductive or developmental toxicant.

Overall, the main critical adverse effects to human health are sensitisation and irritancy.

42.3 Human exposure assessment

42.3.1 Worker exposure

Exposure of workers to ammonium persulfate is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual ammonium persulfate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.214) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.214 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.600	0.026	0.626
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.005	4.74 x 10 ⁻⁵	0.005
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.632
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

42.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to chemicals via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.215) and children (Table D.216).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.215 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.39	N/A	33.39
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻²	1.98 x 10 ⁻²
Swimming in contaminated surface water	2.48 x 10 ⁻³	1.98 x 10 ⁻²	2.23 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			33.432
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.184	N/A	0.184
Bathing in contaminated groundwater	Negligible*	1.02 x 10 ⁻⁴	1.02 x 10 ⁻⁴
Drinking contaminated surface water	3.34 x 10 ⁻⁵	N/A	3.34 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.86 x 10 ⁻⁸	1.86 x 10 ⁻⁸
Swimming in contaminated surface water	2.48 x 10 ⁻⁹	1.99 x 10 ⁻⁸	2.23 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.184
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			3.35 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.216 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E_{oral} (mg/kg bw/day)	E_{derm} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	3.44×10^{-2}	3.44×10^{-2}
Swimming in contaminated surface water	3.47×10^{-2}	3.68×10^{-2}	7.15×10^{-2}
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			116.971
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.645	N/A	0.645
Bathing in contaminated groundwater	Negligible*	1.90×10^{-4}	1.90×10^{-4}
Drinking contaminated surface water	1.17×10^{-4}	N/A	1.17×10^{-4}
Bathing in contaminated surface water	Negligible*	3.45×10^{-8}	3.45×10^{-8}
Swimming in contaminated surface water	3.47×10^{-8}	3.68×10^{-8}	7.16×10^{-8}
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.645
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			1.17×10^{-4}

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

42.4 Human health risk characterisation

42.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No

additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

42.4.2 Occupational health risks

42.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects, such as skin, eye and respiratory irritation and sensitisation by inhalation or skin contact. Given the chemical is delivered to operational sites as a pure solid (1 000 g/L or 100%), the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (0.452 g/L or 0.045%), exposure to the chemical via these fluids is of low concern for workers.

42.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is reduced bodyweight in a 90-day inhalation study where local effects on the respiratory system were also noted. The conservative NOAEL established for these effects is 10.3 mg/m³ (2.1 mg/kg bw/day).

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.217).

Table D.217 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	3
Cleaning and maintenance (hydraulic fracturing)	384
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	3

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.214).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during certain operations (mixing / blending and combined exposures during mixing / blending and cleaning and maintenance).

42.4.3 Public health risks

42.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

42.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and conservative NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.218).

Table D.218 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	0.1	0.02
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak– groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	11	3
Combined exposure from subsurface leak– surface water use Drinking, bathing and swimming in contaminated surface water	6.27×10^4	1.79×10^4

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.215 and Table D.216).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill and to groundwater/surface water contaminated from a leaking storage pond. However, although the MOEs are suggestive of a health concern for adults and children for the scenario involving a subsurface leak from a flowback and / or produced water storage pond, health risks are likely to be mitigated for this scenario considering the chemical fate of ammonium persulfate. This is because the chemical, as an oxidising agent, will most likely be consumed by the reducing environment of the coal seam (The Colorado Department of Labor and Employment Division of Oil and Public Safety 2007) before it travels through groundwater to waters used or consumed by the public. At this point, the chemical will have converted to the more benign ammonium sulfate with component ions (ammonium and

sulfate) that are normal constituents of the human body (Adeva et al. 2012; Institute of Medicine U.S. 2005).

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

42.4.4 Conclusions

42.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for irritation to eyes, skin and respiratory tract, in addition to sensitisation by inhalation or skin contact.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of potential concern for workers from repeated exposures during certain operations. However, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

42.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs suggested a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill and to groundwater/surface water contaminated from a leaking storage pond. However, health risks associated with leakage from a flowback/produced water storage pond will be likely mitigated by degradation of the chemical by the reducing environment of the coal seam.

These public health risks were estimated using conservative exposure modelling (including not considering environmental fate) and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

42.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

42.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

42.5.2 Control measures available to minimise risks to the public

42.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

42.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.
- If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

42.6 References

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- Institute of Medicine U.S. (2004) Dietary reference intakes for water, potassium, sodium, chloride, and sulfate. Chapter 7-Sulfate. The National Academies Press, Bathington D.C. pp 424-448. Accessed in June 2014 at <http://fnic.nal.usda.gov/dietary-guidance/dri-reports/water-potassium-sodium-chloride-and-sulfate>
- NICNAS (2001) Priority Existing Chemical Assessment Report No. 18: Ammonium, Potassium and Sodium Persulfate. Sydney, National Industrial Chemicals Notification and Assessment Scheme.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- The Colorado Department of Labor and Employment Division of Oil and Public Safety (2007) Petroleum Hydrocarbon Remediation by In-situ Chemical Oxidation at Colorado Sites. Accessed in June 2014 at <http://www.colorado.gov/cs/Satellite?blobcol=urldata&blobheader=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251616385451&ssbinary=true>

D43 Sulfurous acid, sodium salt (1:2)

CAS RN	CAS Name
7757-83-7	Sulfurous acid, sodium salt (1:2)

Some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

43.1 Chemical use and concentration

This document from here on refers to Sulfurous acid, sodium salt (1:2) (CAS RN 7757-83-7) as 'sodium sulfite', one of the synonyms of the chemical.

The chemical is used as a component of drilling and hydraulic fracturing fluid formulations for coal seam gas extraction. The chemical's functions within these fluids are confidential business information (CBI).

Prior to incorporation into the final drilling and hydraulic fracturing fluids, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a CBI concentration in drilling formulations and as a liquid at a CBI concentration in hydraulic fracturing formulations. After incorporation, it is present in drilling and hydraulic fracturing fluids at CBI concentrations.

43.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazard was obtained predominantly from the Organisation for Economic Co-operation and Development (OECD 2009), the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers Opinion on inorganic sulfites and bisulfites (SCCNFP 2003), and the Cosmetic Ingredient Review of sulfite compounds (CIR 2003).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sodium sulfite is a severe eye irritant, has low acute oral toxicity in rats, is not a skin irritant, and is not a skin sensitiser.

The critical health effect of the chemical is severe eye irritation. Irritation of the human stomach from sodium sulfite ingestion is possible from the liberation of SO₂ in highly acidic environments.

A No-Observed-Adverse-Effect Level (NOAEL) of 1 670 mg/kg bw/day was established from repeated exposures to the chemical, with systemic effects reported at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 3 230 mg/kg bw/day. This is relevant for non-pregnant workers and the general public.

The most appropriate NOAEL for risk assessment, determined from a developmental toxicity study, is 1 050 mg/kg bw/day based on maternal systemic toxicity (decreased food consumption and decreased bodyweight gain) at the LOAEL of 1 650 mg/kg bw/day.

However, no developmental toxicity occurred at the LOAEL for maternal toxicity or at higher doses. This NOAEL is applicable for pregnant workers and pregnant members of the population.

The chemical is neither genotoxic, carcinogenic, nor a reproductive toxicant.

43.3 Human exposure assessment

43.3.1 Worker exposure

Exposure of workers to sodium sulfite is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of particulates/aerosols during operations. Exposure may also occur from contact with produced water containing residual sodium sulfite.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.219) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling and hydraulic fracturing processes, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.219 Internal doses resulting from chemical exposures associated with drilling and hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via the transport and storage of drilling muds and produced water are negligible (NICNAS 2017a).

43.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling and hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.220) and children (

Table D.221).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.220 Internal doses for ADULTS associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (sodium sulfite in drilling product)			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Accidental bulk spill during transport and surface runoff (sodium sulfite in hydraulic fracturing product)			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.221 Internal doses for CHILDREN associated with drilling and hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff (sodium sulfite in drilling product)			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Accidental bulk spill during transport and surface runoff (sodium sulfite in hydraulic fracturing product)			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking, bathing and swimming in contaminated surface water			
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak – surface water use Drinking and bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

43.4 Human health risk characterisation

43.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

43.4.2 Occupational health risks

43.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as eye irritation. Therefore, the chemical as delivered to operational sites as part of drilling products is of potential concern for workers. However, given the concentration of the chemical as delivered to operational sites in hydraulic

fracturing formulations is lower than the default concentration cut-offs, the chemical in this form is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling and hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids and hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

43.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect is maternal toxicity (decreased food consumption and decreased bodyweight gain) from a developmental toxicity study. The NOAEL established for this effect is 1 050 mg/kg bw/day. This NOAEL is applicable for pregnant workers. Health effects associated with repeated exposure to sodium sulfite is systemic toxicity with a NOAEL of 1 670 mg/kg bw/day established for this effect. This NOAEL is applicable for a general worker.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAELs for these effects with exposures estimated for different occupational activities and combined activities (Table D.222).

Table D.222 Margins of Exposure calculated for drilling and hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE) for pregnant workers	Margin of Exposure (MOE) for general workers
Mixing/blending of drilling chemicals	n.d.	n.d.
Cleaning and maintenance (drilling)	n.d.	n.d.
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.219).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

43.4.3 Public health risks

43.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

43.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical adverse health effects and NOAELs established for these effects, MOEs were calculated for pregnant individuals and the general population for various exposure scenarios (Table D.223 and Table D.224).

Table D.223 Margins of Exposure calculated for different public exposure scenarios for pregnant individuals

Public exposure scenario*	Margin of Exposure (MOE) for pregnant individuals
Accidental bulk spill during transport and surface runoff (sodium sulfite in drilling product)	
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.
Accidental bulk spill during transport and surface runoff (sodium sulfite in hydraulic fracturing product)	
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond (sodium sulfite in hydraulic fracturing product)	
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.220 and

Table D.221).

Table D.224 Margins of Exposure calculated for different public exposure scenarios for the general population

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff (sodium sulfite in drilling product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Accidental bulk spill during transport and surface runoff (sodium sulfite in hydraulic fracturing product)		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond (sodium sulfite in hydraulic fracturing product)		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.220 and

Table D.221)

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for children and pregnant and non-pregnant adults from repeated exposures based on the scenario of an accidental bulk transport spill of the chemical for use in drilling. The MOEs also indicate that the chemical is of low concern for adults and children from repeated exposures for any scenario when the chemical is used in hydraulic fracturing.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of

chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

43.4.4 Conclusions

43.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for eye irritation when used in drilling products only.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

43.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggested a potential concern for adults and children from repeated exposures from a bulk transport spill of the chemical used in drilling. Calculated MOEs indicate a low concern for the public from repeated exposures for scenarios involving the use of the chemical for hydraulic fracturing.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

43.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

43.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

43.5.2 Control measures available to minimise risks to the public

43.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

43.6 References

- CIR (2003) Cosmetic Ingredient Review (CIR) Expert Panel. Final report on the safety assessment of sodium sulfite, potassium sulfite, ammonium sulfite, sodium bisulfite, ammonium bisulfite, sodium metabisulfite and potassium metabisulfite. *Int J Toxicol* 22(suppl 2): 63–88.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- OECD (2009) Screening Information Data Set (SIDS) Initial Assessment Report for SIAM 26: sodium sulfite. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database. Accessed 22 August 2013 at http://webnet.oecd.org/HPV/UI/SIDS_Details.aspx?key=8ee8c5c6-c1b2-4b25-836c-5eb72a45b573&idx=0

SCCNFP (2003) Opinion concerning inorganic sulfites and bisulfites. Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, SCCNFP/0648/03.

D44 Sodium chlorite

CAS RN	CAS Name
7758-19-2	Sodium chlorite

44.1 Chemical use and concentration

Sodium chlorite is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a gel breaker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 100 g/L (10%). After incorporation, it is present in hydraulic fracturing fluid at a default concentration of 10 g/L (1%).

44.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c). The information on health hazards is obtained from the Agency for Toxic Substances and Disease Registry (ATSDR 2004), Organisation for Economic Co-operation and Development (OECD 2009) and a registration dossier on sodium chlorite submitted by industry under the Registration, Evaluation, Authorisation and Restriction of Chemicals program. (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sodium chlorite has moderate acute oral and dermal toxicity, with an oral medial lethal dose (LD50) of 284 mg/kg bw and a dermal (80% slurry) LD50 of 134 mg/kg bw.

Sodium chlorite solutions (31 – 34%) induced no or only mild skin irritation but induced severe eye irritation. Sodium chlorite, when tested as a powder (80%), induced severe skin reactions, including blanching, thickening, necrosis, sloughing, and blackened areas. Sodium chlorite, tested for acute dermal toxicity as a concentrated slurry (80%), also induced severe skin reactions and necrosis, which appeared to enhance systemic uptake. Sodium chlorite was shown not to be a skin sensitiser.

Repeat dose toxicity studies in rats and mice commonly revealed haematological changes with oral sodium chlorite exposures. A guideline 90-day repeated dose toxicity study in rats reported reduced erythrocyte counts, reduced associated erythrocyte parameters and morphological changes in erythrocytes at 80 mg/kg bw/day. At lower doses, minor clinical signs and occasional histopathological abnormalities in the stomach mucosa were seen. A No-Observed-Adverse-Effect Level (NOAEL) for repeated dose oral toxicity was established from this 90-day study at 10 mg/kg bw/day.

Available data suggest that sodium chlorite has low genotoxic potential. Oral studies in rats and mice concluded that sodium chlorite has no carcinogenic potential.

A guideline two-generation reproductive toxicity study in rats also reported haemotoxicity, as well as hepatotoxicity and slight neurobehavioural changes at doses below those associated with no effects in repeated dose studies. The study reported no effects on fertility or

development. Accordingly, a NOAEL for hepatotoxicity was established from this 2-generation study at 3.9 mg/kg bw/day. The LOAEL was approximately 7.6 mg/kg bw/day. This NOAEL is used for this human health risk assessment.

Sodium chlorite was not considered to be teratogenic or a selective developmental toxicant.

44.3 Human exposure assessment

44.3.1 Worker exposure

Exposure of workers to sodium chlorite is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of aerosols during operations. Exposure may also occur from contact with produced water containing residual chemical.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.225) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the summary human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.225 Internal doses resulting from sodium chlorite exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.006	0.003	0.009
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.012	0.001	0.013
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.022

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

44.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised sodium chlorite to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to sodium chlorite via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water.

Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.226) and children (Table D.227).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.226 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻⁴	1.98 x 10 ⁻⁴
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻⁴	4.46 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.340
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	4.074	N/A	4.074
Bathing in contaminated groundwater	Negligible*	2.26 x 10 ⁻⁴	2.26 x 10 ⁻⁴
Drinking contaminated surface water	7.40 x 10 ⁻⁴	N/A	7.40 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	4.11 x 10 ⁻⁸	4.11 x 10 ⁻⁸
Swimming in contaminated surface water	5.49 x 10 ⁻⁸	4.39 x 10 ⁻⁸	9.88 x 10 ⁻⁸
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			4.075
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			7.40 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.227 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻⁴	3.44 x 10 ⁻⁴
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻⁴	3.84 x 10 ⁻⁴
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.691
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	14.260	N/A	14.260
Bathing in contaminated groundwater	Negligible*	4.20 x 10 ⁻⁴	4.20 x 10 ⁻⁴
Drinking contaminated surface water	2.59 x 10 ⁻³	N/A	2.59 x 10 ⁻³
Bathing in contaminated surface water	Negligible*	7.63 x 10 ⁻⁸	7.63 x 10 ⁻⁸
Swimming in contaminated surface water	7.69 x 10 ⁻⁷	8.15 x 10 ⁻⁸	8.50 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			14.260
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.59 x 10 ⁻³

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (see NICNAS 2017a).

44.4 Human health risk characterisation

44.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

44.4.2 Occupational health risks

44.4.2.1 Acute health risks

Health effects information indicates that acute exposure to sodium chlorite as delivered to the site (100 g/L, 10%) is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

Sodium chlorite is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (10 g/L, 1%), exposure to the chemical via these fluids is of low concern for workers.

44.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures to the chemical are haemotoxicity and hepatotoxicity. The NOAEL established for this effect is 3.9 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this NOAEL with exposures estimated for different occupational activities and combined activities (Table D.228).

Table D.228 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	450
Cleaning and maintenance (hydraulic fracturing)	300
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	180

*MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.225).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that sodium chlorite is of low concern for workers from repeated exposures during certain operations.

44.4.3 Public health risks

44.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

44.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

MOEs were calculated for adults and children for various exposure scenarios based on the highest dose without any adverse effect (Table D.229).

Table D.229 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	1	0.30
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	1	0.3
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	5269	1505

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.226 and Table D.227).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures to contaminated surface water from a bulk transport spill, and for repeated exposures to contaminated groundwater/surface water from a leaking storage pond.

However, any health risks arising from exposure from the leaking flowback/produced water storage pond are likely to be mitigated considering the chemical fate of sodium chlorite. This is because the chemical, as an oxidising agent and source of chlorine, will most likely be consumed by the reducing environment of the coal seam (The Colorado Department of Labor and Employment Division of Oil and Public Safety 2007) before it travels through groundwater to waters used or consumed by the public. At this point, the chemical will have converted to the more benign sodium chloride.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

44.4.4 Conclusions

44.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, sodium chlorite, as delivered to operational sites, is of low concern for workers during operations.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

44.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical in concentrated form. Therefore, the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs are suggestive of a potential concern for adults and children in the event of a bulk transport spill, and from repeated exposures to contaminated groundwater/surface water from a leaking storage pond. However, health risks associated with leakage from the flowback/produced water storage pond will be likely mitigated by degradation of the chemical by the reducing environment of the coal seam prior to storage in the pond.

These public health risks were estimated using conservative exposure modelling (including not considering environmental fate) and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

44.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

44.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

44.5.2 Control measures available to minimise risks to the public

44.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

44.5.2.2 Storage of flowback and / or produced water

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond. For such chemicals, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

44.6 References

ATSDR (2004) Toxicological profile for chlorine dioxide and chlorite. Agency for Toxic Substances and Disease Registry (ATSDR), United States Department of Health and Human Services. Accessed September 2013 at <http://www.atsdr.cdc.gov/tfacts160.pdf>

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- The Colorado Department of Labor and Employment Division of Oil and Public Safety (2007) Petroleum Hydrocarbon Remediation by In-situ Chemical Oxidation at Colorado Sites. Accessed in June 2014 at <http://www.colorado.gov/cs/Satellite?blobcol=urldata&blobheader=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1251616385451&ssbinary=true>

D45 Thiosulfuric acid (H₂S₂O₃), disodium salt

CAS RN	CAS Name
7772-98-7	Thiosulfuric acid (H ₂ S ₂ O ₃), disodium salt

45.1 Chemical use and concentration

The document from here on refers to thiosulfuric acid (H₂S₂O₃), disodium salt (CAS RN 7772-98-7) as 'sodium thiosulfate', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a chlorine neutraliser, gel stabiliser, oxygen scavenger or breaker/catalyst.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a liquid at a concentration of 600 g/L (60%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.175 g/L (0.018%).

45.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

Only limited toxicity data were available for sodium thiosulfate. Reliable data for potassium thiosulfate (CAS RN 10294-66-3) and / or ammonium thiosulfate (CAS RN 7783-18-8), both analogues of the sodium compound, were available for the majority of the acute toxicity endpoints. Based on the similarity of chemical structure, properties and biotransformation of the chemicals, the use of data for the other salts, as analogues for sodium thiosulfate, was appropriate to read-across for the endpoints where no data are available for the sodium salt.

In addition, as thiosulfate is a sulfur (VI) oxyanion, the chemical can be grouped with other compounds that, in solution, undergo pH-dependent equilibration reactions between sulfur dioxide, sulfurous acid, bisulfite ion, and sulfite ion. Accordingly, the data gaps for sodium thiosulfate were also read-across from chronic toxicity data available for sodium metabisulfite as a representative compound in this group.

The information on health hazards was sourced primarily from the Registration, Evaluation, Authorisation, and Restriction of Chemicals dossier for sodium thiosulfate (REACH 2013) and the Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report for ammonium compounds (OECD 2008), sodium dithionite (OECD 2006) and disodium disulfite (OECD 2004).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Sodium thiosulfate demonstrates low acute oral toxicity. Based on data available for ammonium thiosulfate and potassium thiosulfate, the chemical has low acute toxicity by dermal and inhalation routes, is not irritating to the skin or eyes, and is not a skin sensitiser.

Irritation of the human stomach from sodium thiosulfate ingestion is possible from the liberation of SO₂ in highly acidic environments.

In a 104-week, combined repeat dose and reproductive study on sodium metabisulfite, a No Observed Adverse Effect Level (NOAEL) of 217 mg/kg bw/day (70 mg/kg bw/day of SO₂ equivalents) was established for local gastrointestinal effects. This NOAEL for localised effects was the equivalent of 180 mg sodium thiosulfate/kg bw/day. Based on the absence of adverse systemic effects observed in repeat dose studies, for the purposes of quantifying the health risk, the highest dose tested in this critical study (180 mg/kg bw/day) is used in this risk assessment of sodium thiosulfate.

The chemical is not genotoxic or a developmental toxicant and, based on data for sodium metabisulfite, is not a carcinogen or toxic to fertility.

45.3 Human exposure assessment

45.3.1 Worker exposure

Exposure of workers to sodium thiosulfate is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical during operations. Exposure may also occur from contact with produced water containing residual sodium thiosulfate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.230) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.230 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.360	0.016	0.376
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic	0.002	1.83 x 10 ⁻⁵	0.002

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
fracturing)			
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.378
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

45.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.231) and children (Table D.232).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.231 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	20.034	N/A	20.034
Bathing in contaminated surface water	Negligible*	1.19 x 10 ⁻²	1.19 x 10 ⁻²
Swimming in contaminated surface water	1.49 x 10 ⁻³	1.19 x 10 ⁻²	1.34 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			20.059
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.071	N/A	0.071
Bathing in contaminated groundwater	Negligible*	3.96 x 10 ⁻⁵	3.96 x 10 ⁻⁵
Drinking contaminated surface water	1.30 x 10 ⁻⁵	N/A	1.30 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	7.19 x 10 ⁻⁹	7.19 x 10 ⁻⁹
Swimming in contaminated surface water	9.61 x 10 ⁻¹⁰	7.69 x 10 ⁻⁹	8.65 x 10 ⁻⁹
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.071
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			1.30 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.232 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	70.119	N/A	70.119
Bathing in contaminated surface water	Negligible*	2.06 x 10 ⁻²	2.06 x 10 ⁻²
Swimming in contaminated surface water	2.08 x 10 ⁻²	2.21 x 10 ⁻²	4.29 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			70.183
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.250	N/A	0.250
Bathing in contaminated groundwater	Negligible*	7.35 x 10 ⁻⁵	7.35 x 10 ⁻⁵
Drinking contaminated surface water	4.53 x 10 ⁻⁵	N/A	4.53 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.33 x 10 ⁻⁸	1.33 x 10 ⁻⁸
Swimming in contaminated surface water	1.35 x 10 ⁻⁸	1.43 x 10 ⁻⁸	2.77 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.250
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			4.54 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

45.4 Human health risk characterisation

45.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No other uncertainty factors are deemed necessary to account for the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

45.4.2 Occupational health risks

45.4.2.1 Acute health risks

Health effects information for 75% solutions of ammonium thiosulfate indicates that acute exposure to sodium thiosulfate at this concentration is unlikely to result in adverse health effects. Therefore, the chemical, as delivered to site (600 g/L, 60%), is of low concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (0.175 g/L, 0.018%), exposure to the chemical via these fluids is of low concern for workers.

45.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 180 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.233).

Table D.233 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	480
Cleaning and maintenance (hydraulic fracturing)	8.50×10^4
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	476

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.230). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and toxicological studies that did not identify a dose of the chemical associated with adverse effects, these MOEs indicate a low concern for workers for repeated exposures under the modelled scenarios.

45.4.3 Public health risks

45.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

45.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.234).

Table D.234 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill–surface water use Drinking, bathing and swimming in contaminated surface water	9	3
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	2523	721
Combined exposure from subsurface leak – surface water use Drinking, bathing and swimming in contaminated surface water	1.39×10^7	3.97×10^6

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.231 and Table D.232). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOEs < 100 derived for repeated public exposures from a bulk transport spill a potential concern cannot be ruled out for adults and children for this modelled scenario. MOEs > 100 for the scenario of repeated public exposures from a leaking storage pond indicate a low concern for adults and children for this modelled scenario.

45.4.4 Conclusions

45.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the chemical as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

45.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk spill, based on the MOEs a potential concern cannot be ruled out for adults and children. For the scenario of environmental contamination from a leaking storage pond, calculated MOEs based on conservative exposure modelling indicate a low concern for adults and children.

45.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

45.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently not classified and is not recommended for classification as a workplace hazardous chemical.

Risk estimates for this chemical suggest that there is low concern for acute or chronic effects to workers from the use of this chemical in coal seam gas operations. No specific risk mitigation recommendations are therefore required.

45.5.2 Control measures available to minimise risks to the public

45.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling do not allow a definitive conclusion regarding the level of concern for adults and children from contamination of surface water from a transport spill.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

45.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- OECD (2006) Screening Information Data Set (SIDS) Initial Assessment Report on sodium dithionite (CAS RN 7775-14-6). Accessed September, 2013 at: <http://webnet.oecd.org/HPV/UI/handler.axd?id=728026e7-08dd-4926-b748-b534c9bb43e1>
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- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on sodium thiosulfate (CAS No: 7772-98-7). European Union. Accessed September 2013 at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.

D46 Peroxydisulfuric acid (((HO)S(O)₂)₂O₂), disodium salt

CAS RN	CAS Name
7775-27-1	Peroxydisulfuric acid (((HO)S(O) ₂) ₂ O ₂), disodium salt

46.1 Chemical use and concentration

The document from here on refers to Peroxydisulfuric acid (((HO)S(O)₂)₂O₂), disodium salt (CAS RN 7775-27-1) as 'sodium persulfate', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a gel breaker.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 1 000 g/kg (100%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.452 g/L (0.045%).

46.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

As they are closely related chemicals, the adverse effects on human health of two persulfates, sodium persulfate (CAS RN 7775-27-1) and ammonium persulfate (CAS RN 7727-54-0), notified as used in the coal seam gas extraction process, were assessed together in a group hazard assessment (NICNAS 2017c). This was on the basis that the two substances are the sodium and ammonium salts of the same persulfate anion, which is an oxidising agent.

Information on sodium persulfate was sourced primarily from the Organisation for Economic Co-operation and Development (OECD 2005) and the NICNAS Priority Existing Chemical Assessment Report No. 18 (NICNAS 2001).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Although sodium persulfate is harmful by the oral route, this potential for acute toxicity is generally not demonstrated via the dermal or inhalation routes. The chemical is non-irritating to slightly irritating to the eyes and respiratory system and is not a skin irritant in animal studies. However, studies in humans indicate a potential for skin and eye irritation.

Sodium persulfate is capable of inducing skin and respiratory sensitisation in animals and these are also the major adverse effects observed in humans. Mouse local lymph node assay (LLNA) results for the chemical suggest it is a moderate to strong sensitiser.

A 90-day dietary study of sodium persulfate in rats showed decreases in body weight at the two highest dose levels. Based on this and pathological findings (limited to the 3 000 ppm group only) consisting of effects on the gastrointestinal tract epithelial lining, a Lowest

Observed Adverse Effect Level (LOAEL) of 3 000 ppm (200 mg /kg bw/day) was established. The next concentration of 1 000 ppm was changed to 5 000 ppm midway through the experiment and therefore a No Observed Adverse Effect Level (NOAEL) could not be established. Inhalation studies for sodium persulfate, which might provide a more conservative NOAEL, were not available. This contrasts with the use of inhalation studies to derive a NOAEL for the closely-related chemical, ammonium persulfate (CAS RN 7727-54-0). An adjustment factor of three is applied to account for the uncertainty in extrapolating from a LOAEL to a NOAEL and therefore an adjusted NOAEL of 67 mg/kg bw/day is used in this risk assessment.

Sodium persulfate is not genotoxic and is not considered a carcinogen. Sodium persulfate is not likely to be a reproductive or developmental toxicant.

Overall, the main critical effects to human health are sensitisation and irritancy.

46.3 Human exposure assessment

46.3.1 Worker exposure

Exposure of workers to sodium persulfate is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual sodium persulfate.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.235) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.235 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.600	0.026	0.626
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Cleaning and maintenance (hydraulic fracturing)	0.005	4.74×10^{-5}	0.005
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.632
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

46.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to chemicals via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.236) and children (

Table D.237).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.236 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	33.390	N/A	33.390
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻²	1.98 x 10 ⁻²
Swimming in contaminated surface water	2.48 x 10 ⁻³	1.98 x 10 ⁻²	2.23 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			33.432
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.184	N/A	0.184
Bathing in contaminated groundwater	Negligible*	1.02 x 10 ⁻⁴	1.02 x 10 ⁻⁴
Drinking contaminated surface water	3.34 x 10 ⁻⁵	N/A	3.34 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	1.86 x 10 ⁻⁸	1.86 x 10 ⁻⁸
Swimming in contaminated surface water	2.48 x 10 ⁻⁹	1.99 x 10 ⁻⁸	2.23 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.184
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			3.35 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible. (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.237 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	116.865	N/A	116.865
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻²	3.44 x 10 ⁻²
Swimming in contaminated surface water	3.47 x 10 ⁻²	3.68 x 10 ⁻²	7.15 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			116.971
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.645	N/A	0.645
Bathing in contaminated groundwater	Negligible*	1.90 x 10 ⁻⁴	1.90 x 10 ⁻⁴
Drinking contaminated surface water	1.17 x 10 ⁻⁴	N/A	1.17 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	3.45 x 10 ⁻⁸	3.45 x 10 ⁻⁸
Swimming in contaminated surface water	3.47 x 10 ⁻⁸	3.68 x 10 ⁻⁸	7.16 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.645
Combined exposure from subsurface leak-surface water use Drinking, bathing and swimming in contaminated surface water			1.17 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible (see NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

46.4 Human health risk characterisation

46.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No other uncertainty factors are deemed necessary to account for the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

46.4.2 Occupational health risks

46.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as skin, eye and respiratory irritation and sensitisation by inhalation or skin contact. Given the chemical is delivered to operational sites as a pure solid (1 000 g/L or 100%), the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (0.452 g/L or 0.045%), exposure to the chemical via these fluids is of low concern for workers.

46.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is decreased bodyweight in a 90-day oral study where local effects on the gastrointestinal tract were also noted. The NOAEL established for these effects is 67 mg/kg bw/day based on an adjusted LOAEL.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the LOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.238).

Table D.238 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	107
Cleaning and maintenance (hydraulic fracturing)	1.22 x 10 ⁴
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	106

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.235).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

46.4.3 Public health risks

46.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

46.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and adjusted NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.239).

Table D.239 Margins of Exposure calculated for hydraulic fracturing public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
<i>Accidental bulk spill and surface runoff</i>		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	2	0.6
<i>Long-term subsurface leak from flowback and / or produced water storage pond</i>		
Combined exposure from subsurface leak– groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	364	104
Combined exposure from subsurface leak– surface water use Drinking, bathing and swimming in contaminated surface water	2.00×10^6	5.72×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.236 and

Table D.237).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, these MOEs are suggestive of a potential concern for adults and children from repeated exposures involving a bulk transport spill. MOEs > 100 for repeated exposures from a leaking flowback/produced water storage pond indicate a low concern for adults and children for this exposure scenario.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

46.4.4 Conclusions

46.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for irritation to eyes, skin and respiratory tract in addition to sensitisation by inhalation or skin contact.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers during operations.

46.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative Tier 1 exposure modelling suggested a potential concern for adults and children from environmental contamination from a bulk transport spill.

These public health risks were estimated using conservative exposure modelling (including not considering environmental fate) and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

46.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

46.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

46.5.2 Control measures available to minimise risks to the public

46.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern for the public from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

46.6 References

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D47 Phosphonium, tributyltetradecyl-, chloride (1:1)

CAS RN	CAS Name
81741-28-8	Phosphonium, tributyltetradecyl-, chloride (1:1)

47.1 Chemical use and concentration

The document from here on refers to phosphonium, tributyltetradecyl-, chloride (1:1) (CAS RN 81741-28-8) as 'TTPC', one of the synonyms of the chemical.

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is in microbial control.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a liquid at a concentration of 100 g/L (10%).

No data were provided in the industry survey for the final concentration of TTPC in fracturing fluid prior to use. The concentration was estimated based on published information reporting biocides as typically used in concentrations ranging from 0.01 - 0.8 g/L (0.001 - 0.08%) (Stringfellow et al. 2014). Based on this information, it is conservatively estimated that the amount of TTPC compared to the total volume of injected hydraulic fracturing fluids is 0.8 g/L (0.08%).

47.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substances (NICNAS 2017c).

Only limited toxicity data were available for TTPC. Three analogue chemicals of TTPC were identified using profiling within the OECD Toolbox. TTPC, tributylhexadecylphosphonium bromide (THPB, CAS RN 14937-45-2), tetrabutylphosphonium chloride (TBPC, CAS RN 2304-30-5) and tetrabutylphosphonium bromide (TBPB, CAS RN 3115-68-2) have similar molecular weights, are used as biocides and are composed of four alkyl chains attached to a functional phosphonium group that is quaternary in nature. In addition, once the chemicals enter the body, they will dissociate into the tetraalkylphosphonium cation and halide anion, with the toxicity of the chemicals attributable to the tetraalkylphosphonium cation. Therefore, the use of data for THPB, TBPC and TBPB as analogues for TTPC, was appropriate to read-across for the endpoints where no data were available for TTPC.

The information on health hazards of TTPC was obtained from data submitted by Cytec Industries Inc. to the US EPA under the Toxic Substances Control Act Section 8(E) (US EPA 2012). Analogue data were obtained from Dunn et al. (1982) and the United States Environmental Protection Agency (US EPA 1978, 1979, 1992a, 1992b, 1992c, 1992d, 1992e).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

TTPC demonstrates high acute toxicity by the inhalation route. Based on read-across data available from THPB, TBPC and TBPB, the chemical is expected to have moderate acute toxicity by oral and dermal routes, will be corrosive to the skin and eyes, and will be a respiratory irritant. Data available for TBPC and TBPB respectively indicate that the chemical is not a skin sensitiser nor is it genotoxic.

No repeat dose, carcinogenicity or reproductive toxicity data were available for the chemical or analogues. Chronic exposure may be considered unlikely given the nature of TTPC and analogues as directly acting corrosives mediating severe adverse effects at the site of contact.

In conclusion, the critical adverse health effect of TTPC is its acute inhalation toxicity.

47.3 Human exposure assessment

47.3.1 Worker exposure

Exposure of workers to TTPC is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical during operations. Exposure may also occur from contact with produced water containing residual TTPC.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered, as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.240) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.240 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.060	0.003	0.063
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.010	8.38 x 10 ⁻⁵	0.010

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.072
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

47.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined

from the hazard characterisation. Separate internal doses were derived for adults (Table D.241) and children (Table D.242).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.241 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	3.339	N/A	3.339
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻³	1.98 x 10 ⁻³
Swimming in contaminated surface water	2.48 x 10 ⁻⁴	1.98 x 10 ⁻³	2.23 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			3.343
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	0.326	N/A	0.326
Bathing in contaminated groundwater	Negligible*	1.81 x 10 ⁻⁴	1.81 x 10 ⁻⁴
Drinking contaminated surface water	5.92 x 10 ⁻⁵	N/A	5.92 x 10 ⁻⁵
Bathing in contaminated surface water	Negligible*	3.29 x 10 ⁻⁸	3.29 x 10 ⁻⁸
Swimming in contaminated surface water	4.39 x 10 ⁻⁹	3.51 x 10 ⁻⁸	3.95 x 10 ⁻⁸
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			0.326
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			5.93 x 10 ⁻⁵

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water. (see NICNAS 2017a).

Table D.242 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	11.687	N/A	11.687
Bathing in contaminated surface water	Negligible*	3.44 x 10 ⁻³	3.44 x 10 ⁻³
Swimming in contaminated surface water	3.47 x 10 ⁻³	3.68 x 10 ⁻³	7.15 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			11.697
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.141	N/A	1.141
Bathing in contaminated groundwater	Negligible*	3.36 x 10 ⁻⁴	3.36 x 10 ⁻⁴
Drinking contaminated surface water	2.07 x 10 ⁻⁴	N/A	2.07 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	6.10 x 10 ⁻⁸	6.10 x 10 ⁻⁸
Swimming in contaminated surface water	6.15 x 10 ⁻⁸	6.52 x 10 ⁻⁸	1.27 x 10 ⁻⁷
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.141
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			2.07 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

47.4 Human health risk characterisation

Limited data concerning repeat dose toxicity, carcinogenicity and reproductive toxicity impact on the ability of NICNAS to undertake a more scientifically robust risk assessment. Nonetheless, based on the data that are available, NICNAS has assessed the risks posed by TTPC in this section.

47.4.1 Occupational Health Risks

47.4.1.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects such as lethality upon inhalation, toxicity in contact with the skin and severe skin burns and eye damage. Given the concentration of the chemical as delivered to operational sites (100 g/L or 10%), the chemical is of potential concern for workers during operations based on the potential for all of the effects listed above.

Acute, inadvertent exposures are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (assumed to be 0.8 g/L or 0.08%), acute exposure to the chemical via these fluids is of low concern for workers.

47.4.1.2 Long-term health risks

No long-term, repeated dose studies are available for the chemical or analogues and therefore a No Observed Adverse Effect Level (NOAEL) could not be established for the chemical. The nature and risk of systemic adverse health effects for workers from repeated exposures to TTPC during certain operations is therefore unknown. However, the chemical is a biocide with known adverse health effects. On this basis, the chemical is of potential concern for workers from repeated exposures during operations.

47.4.2 Public health risks

47.4.2.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

47.4.2.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

There is no information on the effects of long-term contact with the chemical. The nature and risk of systemic adverse health effects for adults and children from possible contact with the surface and groundwater containing TTPC is therefore unknown. As noted, the chemical is a biocide with known adverse health effects. On this basis, the chemical is of potential concern for the public from repeated exposures.

47.4.3 Conclusions

Based on the data that are available, NICNAS has assessed the risks posed by TTPC. Limited chronic toxicity data preclude the conduct of a more scientifically robust risk assessment.

47.4.3.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for toxicity via the dermal and inhalation routes, severe skin burns and eye damage.

As information on the systemic adverse health effects from contact with the chemical is not available, the nature and risk of adverse health effects to workers of repeated exposure to the chemical as delivered to operational sites are unknown. On this basis, the chemical is of potential concern for workers.

47.4.3.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

There is no information on the chronic adverse health effects of exposure to the chemical and therefore the nature and risk of systemic adverse health effects for adults and children from repeated exposures via environmental contamination are unknown. As noted, the chemical is a biocide with known adverse health effects. On this basis, the chemical is of potential concern for the public from repeated exposures.

47.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

47.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

47.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for adults and children from repeated exposure to the chemical from water contamination resulting from the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

47.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

47.5.2.2 Storage of flowback and / or produced water

For chemicals for which risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

47.6 References

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D48 Cellulase

CAS RN	CAS Name
9012-54-8	Cellulase

48.1 Chemical use and concentration

As an enzyme of biological origin, cellulase is considered as a substance of unknown or variable composition, complex reaction products or biological material (UVCB).

The enzyme is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is as a gel breaker.

Prior to incorporation into the final hydraulic fracturing fluid, the enzyme as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a solid at a concentration of 150 g/kg (15%).

No data were provided in the industry survey for the final concentration of cellulase in fracturing fluid prior to use; however, information on the proportions of other similar enzyme additives used in fracturing fluids to perform the same function was available from the survey and other industry sources:

- Enzyme (CBI) present at 0.0009 g/L
- Hemicellulase present at 0.0364 g/L, 0 - 0.005 g/L (Australia Pacific LNG 2014)
- Hemicellulase present at 1.1 g/L (New Zealand Petroleum and Minerals 2012)
- Proprietary enzyme present at 0.002 g/L (Australia Pacific LNG 2014).

Based on the highest concentration available from industry sources, it is conservatively estimated that the amount of cellulase compared to the total volume of injected hydraulic fracturing fluids is 1.1 g/L (0.11%).

48.2 Critical health effects

The adverse effects on human health of cellulase (CAS RN 9012-54-8), as used in the coal seam gas extraction process, was assessed in a group together with another enzyme (CAS RN CBI) and hemicellulase (CAS RN 9025-56-3), on the basis of common features described in detail in the hazard assessment (NICNAS 2017a).

Information on health hazards was sourced primarily from the Human and Environmental Risk Assessment on ingredients of household cleaning products (α -amylase, cellulases and lipases) (HERA 2005), the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier submission for cellulase (REACH 2013) as well as a safety evaluation of an alkaline cellulase (Greenough et al. 1991). Reviews published on the toxicology of enzymes used in cleaning products (Basketter et al. 2012) and the Enzymes REACH Consortium (ERC 2010) were used to provide additional data. Published studies were the source of respiratory sensitisation data for cellulase.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Cellulase demonstrates low acute oral and inhalation toxicity and is not irritating to the skin or eye. Limited animal data indicate that cellulase is not a skin sensitiser; however, it is capable of inducing respiratory sensitisation in humans who are occupationally exposed.

Cellulase has low repeat oral dose toxicity. The critical study is a 13-week dietary study in rats, where no adverse effects were seen at a top dose of 3 000 mg/kg bw/day. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk, the highest dose tested in the critical study (3 000 mg/kg bw/day) is used in this risk assessment.

Cellulase is neither genotoxic nor a developmental toxicant. The carcinogenic potential of the substance is unknown, but carcinogenicity is not expected for enzymes in general.

Overall, the main critical adverse effect to human health is respiratory sensitisation.

48.3 Human exposure assessment

48.3.1 Worker exposure

Exposure of workers to cellulase is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual cellulase. Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with enzyme handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the enzyme as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the enzyme as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.243) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a). As absorption of the enzyme through the skin is considered to be negligible, the internal dose via the dermal route is estimated as zero. Consequently, the absorbed dose via the inhalation route is considered to be the total internal dose.

Table D.243 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0	0.004	0.004

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0	0.001	0.001
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.005
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

48.3.1.1 Public exposure

The public may be exposed to the enzyme via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the enzyme to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the enzyme via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

Moreover, since the oral and dermal absorption of the enzyme is considered to be negligible (NICNAS 2017b), modelling of different public exposure scenarios was not considered further as any resulting internal human doses will, by definition, be negligible.

Overall, no public exposure to the enzyme via any of the exposure scenarios described above is expected, and therefore exposure estimates are not presented.

48.4 Human health risk characterisation

48.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

48.4.2 Occupational health risks

48.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure enzyme will result in adverse health effects, such as respiratory sensitisation. Given the concentration of the enzyme as delivered to operational sites (150 g/kg or 15%), the enzyme in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the enzyme (if required) and during manipulation of equipment containing residual enzyme during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The enzyme is a component of hydraulic fracturing fluids. Similarly to exposures to the enzyme as delivered to operational sites, levels of exposure to cellulase in these fluids will vary depending on work practices. Given the concentration in hydraulic fracturing fluids (assumed to be 1.1 g/L or 0.11%), exposure to the enzyme via these fluids is of low concern for workers.

48.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the enzyme at any dose tested, up to 3 000 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.244).

Table D.244 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	7.64×10^5
Cleaning and maintenance (hydraulic fracturing)	2.86×10^6
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	6.03×10^5

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.243). ** The MOEs were calculated based on a NOAEL for which no adverse effects have been observed in all of the doses tested.

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and a toxicological study that did not demonstrate any adverse effects at any of the doses examined, these MOEs indicate a low concern for workers from repeated exposures under the modelled scenarios.

48.4.3 Public health risks

48.4.3.1 Acute health risks

Given industrial use of the enzyme for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the enzyme in this form is of low concern for the public.

48.4.3.2 Long-term health risks

The public is most likely to come into contact with the enzyme via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the absence of reported adverse health effects, which is consistent with the lack of uptake of the enzyme by the oral or dermal routes, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

48.4.4 Conclusions

48.4.4.1 Occupational health risks

The enzyme as delivered to operational sites is of potential concern for workers during operations based on the potential for respiratory sensitisation. Exposure to the enzyme via hydraulic fracturing fluids is of low concern for workers.

The absence of adverse health effects upon repeated exposure indicate that the substance as delivered to operational sites is of low concern for workers during operations. Also, repeated exposure to the enzyme via hydraulic fracturing fluids is of low concern for workers.

48.4.4.2 Public health risks

The public is unlikely to come into contact with the enzyme as delivered to operational sites and so the enzyme in this form is of low concern for the public.

Furthermore, based on the absence of reported adverse health effects from repeated exposures, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

48.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

48.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the enzyme is currently classified as a workplace hazardous chemical.

Risk estimates for this enzyme suggest a potential concern for workers.

For such substances, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of enzymes. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this enzyme, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the enzyme depend on the physical form and the manner in which the chemical is used. Information on control measures is available in the human health risk assessment summary report (NICNAS 2017b).

48.6 References

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D49 Hemicellulase

CAS RN	CAS Name
9025-56-3	Hemicellulase

49.1 Chemical Use and Concentration

As an enzyme of biological origin, hemicellulase is considered as a substance of unknown or variable composition, complex reaction products or biological material (UVCB).

The enzyme is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is confidential business information (CBI).

Prior to incorporation into the final hydraulic fracturing fluid, the enzyme as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a solid at a concentration of 1 200 g/kg (100%). After incorporation, it is present in hydraulic fracturing fluid at a concentration of 0.0364 g/L (0.004%).

49.2 Critical Health Effects

The adverse effects on human health of hemicellulase (CAS RN 9025-56-3) as used in the coal seam gas extraction process was assessed in a group, together with cellulase (CAS RN 9012-54-8) and another enzyme (CAS RN CBI), on the basis of common features described in detail in the hazard assessment (NICNAS 2017c).

Information on health hazards was sourced primarily from the Human and Environmental Risk Assessment on ingredients of household cleaning products (α -amylase, cellulases and lipases) (HERA 2005), the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier submissions for cellulase (REACH 2013a) and enzyme (REACH 2013b) as well as a safety evaluation of an alkaline cellulase (Greenough et al. 1991). Reviews published on the toxicology of enzymes used in cleaning products (Basketter et al. 2012) and the Enzymes REACH Consortium (ERC 2010) were also used to provide additional data. Published studies were the primary source of respiratory sensitisation data for hemicellulase.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Only limited data are available for hemicellulase, but it is expected that its toxicity profile will be very similarly to that of the related UVCBs, cellulase and enzyme (CBI).

Based on available studies of cellulase and another enzyme (CBI), hemicellulase is of low acute oral and inhalation toxicity and is not irritating to the skin or eyes. Hemicellulase is capable of inducing respiratory sensitisation in humans who are occupationally exposed. Animal data indicate that cellulase is not a skin sensitiser, and similarly hemicellulase is not expected to have skin sensitising potential.

Supporting data for cellulase and another enzyme (CBI) indicate that hemicellulase has low repeat oral dose toxicity. Specifically, toxicity data for cellulase were used for evaluation of the critical (most sensitive) health effect for repeated exposures to hemicellulase as the two enzymes were more closely related than were hemicellulase the other and enzyme (CBI)

(NICNAS 2017c). In addition, a 13-week dietary study of cellulase in rats showed no adverse effects at a top dose of 3 000 mg/kg bw/day, whereas in a gavage study of enzyme (CBI), the top dose tested was only 75 mg/kg bw/day. Based on the absence of adverse effects observed in any repeat dose toxicity study, for the purposes of quantifying the health risk, the highest dose tested in the cellulase study (3 000 mg/kg bw/day) is used in this risk assessment for hemicellulase.

Cellulase and another enzyme (CBI) do not possess genotoxic potential, and the former is not a developmental toxicant. Similarly, hemicellulase is not considered a genotoxin or developmental toxicant.

The carcinogenic potential of the three UVCBs is unknown, but carcinogenicity is not expected for enzyme preparations in general.

Overall, the main critical adverse effect to human health is respiratory sensitisation.

49.3 Human exposure assessment

49.3.1 Worker exposure

Exposure of workers to hemicellulase is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual hemicellulase.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with enzyme handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the enzyme as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the enzyme as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.245) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a). As absorption of the enzyme through the skin is considered to be negligible, the internal dose via the dermal route is estimated as zero. Consequently, the absorbed dose via the inhalation route is considered to be the total internal dose.

Table D.245 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0	0.031	0.031
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0	3.81 x 10 ⁻⁶	3.81 x 10 ⁻⁶
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.031
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} – Internal dose from inhalation exposure; E_{total} – Total internal dose all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

49.3.2 Public exposure

The public may be exposed to the enzyme via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air. The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the enzyme to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the enzyme via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

Moreover, since the oral and dermal absorption of the enzyme is considered to be negligible (NICNAS 2017c), modelling of different public exposure scenarios was not considered further as any resulting internal human doses will, by definition, be negligible. Overall, no public exposure to the enzyme via any of the exposure scenarios described above is expected, and therefore exposure estimates are not presented.

49.4 Human health risk characterisation

49.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

49.4.2 Occupational health risks

49.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure enzyme will result in adverse health effects such as respiratory sensitisation. Given the concentration of the enzyme as delivered to operational sites (1 200 g/kg or 100%), the enzyme in this form is of potential concern for workers.

Acute, inadvertent exposures are most likely during manual handling of the enzyme (if required) and during manipulation of equipment containing residual enzyme during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The enzyme is a component of hydraulic fracturing fluids. Similarly to exposures to the enzyme as delivered to operational sites, levels of exposure to hemicellulase in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids (0.0364 g/L or 0.004%), exposure to the enzyme via these fluids is of low concern for workers.

49.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the analogue enzyme, cellulase, at any dose tested up to 3 000 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities (Table D.246).

Table D.246 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	9.55 x 10 ⁴
Cleaning and maintenance (hydraulic fracturing)	7.87 x 10 ⁸
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	9.54 x 10 ⁴

** MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.245). ** The MOEs were calculated based on a NOAEL for which no adverse effects have been observed in all of the doses tested.*

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and toxicological studies that did not identify a dose of the enzyme associated with adverse effects, these MOEs indicate a low concern for workers from repeated exposures under the modelled scenarios.

49.4.3 Public health risks

49.4.3.1 Acute health risks

Given industrial use of the enzyme for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the enzyme in this form is of low concern for the public.

49.4.3.2 Long-term health risks

The public is most likely to come into contact with the enzyme via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the absence of reported adverse health effects, which is consistent with the lack of uptake of the enzyme by the oral or dermal routes, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

49.4.4 Conclusions

49.4.4.1 Occupational health risks

The enzyme as delivered to operational sites is of potential concern for workers during operations based on the potential for respiratory sensitisation. Exposure to the enzyme via hydraulic fracturing fluids is of low concern for workers.

The absence of adverse health effects upon repeated exposure indicate that the substance as delivered to operational sites is of low concern for workers during operations. Also, repeated exposure to the enzyme via hydraulic fracturing fluids is of low concern for workers.

49.4.4.2 Public health risks

The public is unlikely to come into contact with the enzyme as delivered to operational sites and so the enzyme in this form is of low concern for the public.

Furthermore, based on the absence of reported adverse health effects from repeated exposures, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

49.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

49.5.1 *Obligations under workplace health and safety legislation*

As noted in the hazard assessment report (NICNAS 2017c), this enzyme requires classification as a hazardous workplace chemical. Accordingly, the classification of the enzyme has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this enzyme suggest a potential concern for workers.

For such substances, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of enzymes. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this enzyme, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the enzyme depend on the physical form and the manner in which the enzyme is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

49.6 References

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D50 Alkanes, C12-C26-branched and linear

CAS RN	CAS Name
90622-53-0	Alkanes, C12-C26-branched and linear

50.1 Chemical use and concentration

Alkanes, C12-26-branched and linear (CAS RN 90622-53-0) is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB). The substance is a petroleum product.

The substance is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its reported function within these fluids is as a gelling agent.

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a concentration of 520 g/L (52%). No product information was available from industry survey.

After incorporation, it is present in hydraulic fracturing fluid at a concentration of 2.6 g/L (0.26%) (NICNAS 2017b).

50.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

Limited health hazard data were available for the substance. Therefore, read-across of data from two substances, hydrodesulfurised middle petroleum distillates (CAS RN 64742-80-9) and hydrotreated middle petroleum distillates (CAS RN 64742-46-7) were used to build a human health hazard profile for the substance. These data were obtained predominantly from the Registration, Evaluation, Authorisation and Restriction of Chemicals dossiers of the substance and its analogues (REACH 2013a, 2013b, 2013c).

Alkanes, C12-C26-branched and linear is expected to have low acute oral, dermal and inhalation toxicity, has skin irritant effects, is not an eye irritant or a skin sensitiser, based on reading across data available for hydrodesulfurised middle petroleum distillates.

A No-Observed-Adverse-Effect Level (NOAEL) was not established for systemic toxicity at a dose of up to 2 000 mg/kg bw/day from 28-day studies available for hydrodesulfurised middle petroleum distillates. An adjustment factor of three is applied for inadequate duration of these studies. Consequently, based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk of the substance, this highest adjusted dose tested in the critical study (667 mg/kg bw/day) is used in this risk assessment.

The substance is neither genotoxic, based on reading across data available for hydrodesulfurised middle petroleum distillates; nor carcinogenic, based on reading across data available for hydrotreated middle petroleum distillates.

Nonetheless, as the content of potential carcinogenic impurities in Alkanes, C12-C26-branched and linear is not known, and since hydrodesulfurised middle petroleum distillates and hydrotreated middle petroleum distillates all belong to the same petroleum group, Other Gas Oils, the three substances are expected to possess similar properties (CONCAWE 2012; European Union Council 1993). All the category members of the Other Gas Oils group are classified similarly as substances that should be regarded as if they are carcinogenic to humans under the Approved Criteria for Classifying Hazardous Substances (Carcinogenic Category 1B, NOHSC 2004) and in the European Union Harmonised CLP Regulation [Category 2 carcinogens, Annex VI of Regulation (EC) No. 1272/2008], unless information is available on the refining history demonstrating that the substances produced from refining are not carcinogenic.

The existing hazard classification of the substance in the Hazardous Substances Information System (HSIS) (Safe Work Australia 2013) is Category 2 carcinogen which includes two notes appended as follows:

- Note N – ‘The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.’
- Note H – ‘The classification and label shown for this substance applies to the dangerous property(ies) indicated by the Risk Phrase(s) in combination with the category(ies) of danger shown. The manufacturers, distributors and importers of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of Section 7 of Annex VI of directive 67/548/EEC.’

Although the data available for the analogue (hydrotreated middle petroleum distillates) of the substance do not support this classification, the limited information on the full refining history of alkanes, C12-C26-branched and linear or its analogues is not sufficient to recommend removal of the current HSIS classification.

50.3 Human exposure assessment

50.3.1 Worker exposure

Exposure of workers to the substance is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of the volatilised substance/aerosols during operations. Exposure may also occur from contact with produced water containing residual substance.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities – mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.247) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.247 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	0.312	0.084	0.396
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	0.031	0.002	0.033
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			0.429
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

50.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised substance/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the substance via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.248) and children (Table D.249).

Table D.249).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.248 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	5.009	N/A	5.009
Bathing in contaminated surface water	Negligible*	2.97 x 10 ⁻³	2.97 x 10 ⁻³
Swimming in contaminated surface water	3.72 x 10 ⁻⁴	2.97 x 10 ⁻³	3.34 x 10 ⁻³
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			5.015
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible*
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	1.059	N/A	1.059

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Bathing in contaminated groundwater	Negligible*	5.89 x 10 ⁻⁴	5.89 x 10 ⁻⁴
Drinking contaminated surface water	1.92 x 10 ⁻⁴	N/A	1.92 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	1.07 x 10 ⁻⁷	1.07 x 10 ⁻⁷
Swimming in contaminated surface water	1.43 x 10 ⁻⁸	1.14 x 10 ⁻⁷	1.28 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			1.06
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			1.93 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.249 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	17.530	N/A	17.530
Bathing in contaminated surface water	Negligible*	5.16 x 10 ⁻³	5.16 x 10 ⁻³
Swimming in contaminated surface water	5.20 x 10 ⁻³	5.52 x 10 ⁻³	1.07 x 10 ⁻²
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			17.546
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible* *	Negligible**	Negligible* *
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	3.71	N/A	3.71
Bathing in contaminated groundwater	Negligible*	1.09 x 10 ⁻³	1.09 x 10 ⁻³

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking contaminated surface water	6.73 x 10 ⁻⁴	N/A	6.73 x 10 ⁻⁴
Bathing in contaminated surface water	Negligible*	1.98 x 10 ⁻⁷	1.98 x 10 ⁻⁷
Swimming in contaminated surface water	2.00 x 10 ⁻⁷	2.12 x 10 ⁻⁷	4.12 x 10 ⁻⁷
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			3.71
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			6.74 x 10 ⁻⁴

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

50.4 Human health risk characterisation

50.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

50.4.2 Occupational health risks

50.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the substance (if required) and during manipulation of equipment containing the residual substance during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the assumed low concentration in hydraulic fracturing fluids (10 g/L, 1%), exposure to the chemical via these fluids is of low concern for workers.

50.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at an adjusted dose tested of 667 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest adjusted no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.250).

Table D.250 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	1686
Cleaning and maintenance (hydraulic fracturing)	20291
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	1557

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.247). ** In the absence of a NOAEL, these MOEs were calculated based on the highest adjusted dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations. However, noting the expectation that Alkanes, C12-C26-branched and linear is carcinogenic unless information is available on the refining history demonstrating that the substances produced from refining are not carcinogenic, the substance is of potential concern regarding carcinogenicity for workers from repeated exposures for the modelled exposure scenarios.

50.4.3 Public health risks

50.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

50.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the highest adjusted dose at which no adverse effects were noted, MOEs were calculated for adults and children for various exposure scenarios (Table D.251).

Table D.251 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	133	38

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	629	180
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	3.46×10^6	9.89×10^5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.248 and

Table D.249). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOEs < 100 derived for repeated exposures to children for the bulk transport spill scenario, a potential concern for children for this scenario cannot be ruled out. Based on conservative exposure modelling of environmental contamination, the MOEs > 100 for adults for the bulk transport spill and for adults and children for the leaking storage pond scenario indicate a low concern.

Again, noting the expectation that Alkanes, C12-C26-branched and linear is carcinogenic unless information is available on the refining history demonstrating that the substances produced from refining are not carcinogenic, the substance is of potential concern regarding carcinogenicity for the public from repeated exposures for the modelled exposure scenarios.

50.4.4 Conclusions

50.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the chemical as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations. However, because of the carcinogenic potential of the chemical, it is regarded as posing a risk to workers unless the refining history demonstrates that the substances produced from refining are not carcinogenic.

50.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures via environmental contamination, MOEs > 100 based on conservative exposure modelling indicate a low concern for adults for the bulk transport spill and storage pond leak scenarios and for children for the storage pond leak scenario. Based on MOEs of < 100, a potential concern for children for the bulk spill scenario cannot be ruled out. Additionally, overall, there is a potential concern for the public regarding carcinogenicity unless the refining history for the chemical demonstrates that the substances produced from refining are not carcinogenic.

50.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

50.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects potentially via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

50.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for the public from repeated exposure to the chemical from water contamination resulting from some of the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

50.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

50.5.2.2 Storage of flowback and / or produced water

For chemicals where there is a potential concern from contamination of shallow groundwater from a leaking storage pond, the following risk mitigation measures are available (NICNAS 2017b).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

50.6 References

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- REACH (2013c) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on distillates (petroleum), hydrotreated middle (CAS RN 64742-46-7). European Union. Accessed 27 September 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.
- Safe Work Australia (2013) Hazardous Substances Information System (HSIS). Accessed 23 September 2013 at <http://hsis.safeworkaustralia.gov.au/HazardousSubstance>

D51 2-Ethylhexanol heavies

CAS RN	Chemical Name
CBI	2-Ethylhexanol heavies

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

51.1 Chemical use and concentration

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final drilling fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in drilling fluid at a CBI concentration.

51.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was sourced primarily from a Registration, Evaluation, Authorisation and Restriction of Chemicals dossier submission (REACH 2013), an IUCLID dataset for the chemical (EC 2000) and a Joint European Community Food Additive monograph (OrganisationWHO 2013).

The critical (most sensitive) adverse health effects from the NICNAS hazard assessment are summarised below.

The chemical has low acute oral and dermal toxicity but can be considered moderately toxic by inhalation. The chemical is corrosive to the skin and eyes but is not expected to be a skin sensitiser.

The critical adverse health effects from repeated exposures to the chemical were changes to several organs, in particular the kidney, stomach and liver. The most appropriate No Observed Adverse Effect Level (NOAEL) for these systemic effects is 50 mg/kg bw/day based on reduced body weight gain and increases in relative organ weights in a two-year carcinogenicity study in rats.

The chemical is not genotoxic or carcinogenic based on the available data, but did induce effects on fertility (testes) at high dose levels. In an oral developmental toxicity study, a NOAEL of 130 mg/kg bw/day was determined based on foetotoxicity (reduced foetal body weights and increased skeletal malformations) noted in the absence of signs of marked maternal toxicity.

51.3 Human exposure assessment

51.3.1 Worker exposure

Exposure of workers to the chemical is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols or volatilised chemical during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of chemicals as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.252) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.252 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport of drilling muds are negligible (NICNAS 2017a).

51.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the volatilised chemical/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to chemicals via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.253) and children (Table D.254).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.253 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.254 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

51.4 Human health risk characterisation

51.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

51.4.2 Occupational health risks

51.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical will result in adverse health effects from inhalation, severe skin burns and eye damage, and possible risk of harm to the unborn child. However, given the low concentration of the chemical as delivered to operational sites, the chemical in this form is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing residual chemical during operations, cleaning and maintenance, and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the even lower concentration in drilling fluids, exposure to the chemical via these fluids is of low concern for workers.

51.4.2.2 Long-term health risks

From the hazard characterisation, the critical adverse health effect for repeated exposures to the chemical is reduced bodyweight gain and increases in relative organ weights. The NOAEL established for these effects is 50 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.255).

Table D.255 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	n.d.
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

* MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.252). n.d. – not disclosed.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations. Given that the NOAEL for foetotoxic effects is at a higher dose (130 mg/kg bw/day) than for systemic effects, the chemical is of even lower concern for foetotoxic effects, which is relevant to pregnant workers.

51.4.3 Public health risks

51.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

51.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect of systemic toxicity for which a NOAEL of 50 mg/kg bw/day was established, MOEs were calculated for adults and children for various exposure scenarios (Table D.256).

Table D.256 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern (reduced bodyweight gain and increases in relative organ weights) for children (but not for adults) from repeated exposures based on the modelled exposure scenario of a bulk transport spill. Given that the NOAEL for foetotoxic effects is at a higher dose (130 mg/kg bw/day) than for these systemic effects, the chemical is of low concern for this adverse effect which is relevant for pregnant adults.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative Tier 1 exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

51.4.4 Conclusions

51.4.4.1 Occupational health risks

Despite the acute adverse health effects, the chemical as delivered to operational sites is of low concern for workers during operations due to its low concentration. Also, exposure to the substance via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

51.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs are suggestive of a potential concern for children, based on the modelled exposure scenario of a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

51.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

51.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

51.5.2 Control measures available to minimise risks to the public

51.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a)

51.6 References

- EC (2000) European Commission: European chemical Substances Information System (ESIS). IUCLID Dataset, European Chemicals Bureau. Accessed November 2013 at <http://esis.jrc.ec.europa.eu/>
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). European Union. Accessed November 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>
- WHO (2013) Toxicological evaluation of certain food additives and food contaminants. World Health Organisation (WHO) Food Additives Series (Report of the Joint FAO/WHO

Expert Committee on Food Additives) World Health Organisation. Accessed November 2013 at <http://www.inchem.org/pages/jecfa.html>.

D52 Amine salt

CAS RN	Chemical Name
CBI	Amine salt

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

52.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

52.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the Organisation of Economic Co-operation and Development (OECD 2012) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH 2013). This chemical was assessed as part of a group assessment with Quaternary amine (CAS RN CBI) for which read-across was applied to some of the toxicity endpoints for this chemical.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The chemical has low acute oral toxicity and is a skin and eye irritant. Based on read-across from the data for quaternary amine, amine salt has low acute dermal toxicity, low to moderate acute inhalation toxicity, and is a respiratory tract irritant. Based on read-across data for a category, amine salt is not expected to be a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment of amine salt is 100 mg/kg bw/day based on systemic effects at the No-Observed-Adverse-Effect Level (LOAEL) of 190 mg/kg bw/day.

Amine salt, based on read-across data for quaternary amine, is not genotoxic or carcinogenic, and is not a reproductive toxicant.

52.3 Human exposure assessment

52.3.1 Worker exposure

Exposure of workers to the chemical is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual chemical and / or its salts.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.257) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.257 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

52.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.258) and children (Table D.259).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.258 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.259 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

52.4 Human health risk characterisation

52.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

52.4.2 Occupational health risks

52.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical or a concentrated solution will result in adverse health effects such as acute inhalation toxicity, and skin, eye and respiratory irritation. However, given the low concentration of the chemical as delivered to operational sites, the chemical in this form is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the even lower concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

52.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the chemical is systemic toxicity. The NOAEL established for this effect is 100 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.260).

Table D.260 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.257).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations

52.4.3 Public health risks

52.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

52.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.261).

Table D.261 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.258 and Table D.259).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

52.4.4 Conclusions

52.4.4.1 Occupational health risks

Given the low concentration of the chemical as delivered to operational sites, the chemical is of low concern for workers despite its known acute health hazards. Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

52.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

52.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

52.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

52.5.2 Control measures available to minimise risks to the public

52.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

52.6 References

ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation Version 2.1 November 2012. European Chemicals Agency

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on the chemical. Accessed 3 September 2013 <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D53 Enzyme

CAS RN	Chemical Name
CBI	Enzyme

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

53.1 Chemical use and concentration

As an enzyme of biological origin, this enzyme is considered as a substance of unknown or variable composition, complex reaction products or biological material (UVCB).

The enzyme is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the enzyme as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled at a CBI concentration. The physical state of the transported enzyme was not reported. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

53.2 Critical health effects

The adverse effects on human health of the enzyme as used in the coal seam gas extraction process were assessed in a group, together with cellulase (CAS RN 9012-54-8) and hemicellulase (CAS RN 9025-56-3). This was on the basis of common features described in detail in the hazard assessment (NICNAS 2017c).

Information on health hazards was sourced primarily from the Human and Environmental Risk Assessment (HERA) on ingredients of household cleaning products (α -amylase, cellulases and lipases) (HERA 2005) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier submission for enzyme (REACH 2013). Reviews published on the toxicology of enzymes used in cleaning products (Basketter et al. 2012) and the Enzymes REACH Consortium (ERC 2010) were also used to provide additional data. Published respiratory sensitisation studies for cellulase and hemicellulase were read-across to provide supporting data for this enzyme.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Only limited data are available for the enzyme but it is expected that its toxicity profile will be very similarly to that of the related UVCBs, cellulase and hemicellulase.

The enzyme demonstrates low acute oral and inhalation toxicity and is not irritating to the skin or eyes. Based on animal data available for cellulase, the enzyme is not likely to be a skin sensitiser. As both cellulase and hemicellulase are capable of inducing respiratory

sensitisation in humans who are occupationally exposed, it is expected that this enzyme is also a respiratory sensitiser.

The enzyme has low repeat oral dose toxicity, with no signs of systemic toxicity, in a 90-day gavage study in rats at the highest dose tested of 75 mg/kg bw/day. Based on the absence of adverse effects observed in any repeat dose toxicity study, for the purposes of quantifying the health risk, the highest dose tested in the critical study (75 mg/kg bw/day) is used in this risk assessment.

Cellulase and this enzyme are not genotoxic and the former is not a developmental toxicant. Similarly, this enzyme is not considered a developmental toxicant. The carcinogenic potential of the enzyme is unknown, but carcinogenicity is not expected for enzymes in general.

Overall, the main critical adverse effect to human health is respiratory sensitisation.

53.3 Human exposure assessment

53.3.1 Worker exposure

Exposure of workers to the enzyme is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual enzyme. Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with enzyme handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the enzyme as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the enzyme as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.262) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b). As absorption of the enzyme through the skin is considered to be negligible, the internal dose via the dermal route is estimated as zero. Consequently, the absorbed dose via the inhalation route is considered to be the total internal dose.

Table D.262 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* - Internal dose from inhalation exposure; *E_{total}* - Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water storage are negligible (NICNAS 2017a).

53.3.2 Public exposure

The public may be exposed to the enzyme via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air. The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the enzyme to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the enzyme via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

Moreover, since the oral and dermal absorption of the enzyme is considered to be negligible (NICNAS 2017a), modelling of different public exposure scenarios was not considered further as any resulting internal human doses will, by definition, be negligible.

Overall, no public exposure to the enzyme via any of the exposure scenarios described above is expected, and therefore exposure estimates are not presented.

53.4 Human health risk characterisation

53.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

53.4.2 Occupational health risks

53.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure enzyme will result in adverse health effects such as respiratory sensitisation. Given the concentration of the chemical as delivered to operational sites, the chemical in this form is of potential concern for workers, noting that the physical state of the enzyme as delivered to the site is not known.

Acute, inadvertent exposures are most likely during manual handling of the enzyme (if required) and during manipulation of equipment containing residual enzyme during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The enzyme is a component of hydraulic fracturing fluids. Similarly to exposures to the enzyme as delivered to operational sites, levels of exposure to the enzyme in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the enzyme via these fluids is of low concern for workers.

53.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the enzyme at any dose tested, up to 75 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities (Table D.263).

Table D.263 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.262). ** The MOEs were calculated based on a NOAEL for which no adverse effects have been observed in all of the doses tested.*

Based on uncertainty factors derived from risk characterisation, conservative assumptions within the exposure modelling and a toxicological study that did not identify a dose of the

enzyme associated with adverse effects, the MOEs indicate a low concern for workers from repeated exposures under the modelled scenarios.

53.4.3 Public health risks

53.4.3.1 Acute health risks

Given industrial use of the enzyme for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the enzyme in this form is of low concern for the public.

53.4.3.2 Long-term health risks

The public is most likely to come into contact with the enzyme via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the absence of reported adverse health effects, consistent with the lack of uptake of the enzyme by the oral or dermal routes, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

53.4.4 Conclusions

53.4.4.1 Occupational health risks

The enzyme as delivered to operational sites is of potential concern for workers during operations based on the potential for respiratory sensitisation. Exposure to the enzyme via hydraulic fracturing fluids is unlikely to pose an acute health risk for workers.

The absence of adverse health effects upon repeated exposure indicate that the substance as delivered to operational sites is of low concern for workers during operations. Also, repeated exposure to the enzyme via hydraulic fracturing fluids or produced water is of low concern for workers.

53.4.4.2 Public health risks

The public is unlikely to come into contact with the enzyme as delivered to operational sites and so the enzyme in this form is of low concern for the public.

Furthermore, the enzyme is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

53.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

53.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the enzyme requires classification as a workplace hazardous chemical. Accordingly, the classification of the enzyme has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this enzyme suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

For chemicals with serious health effects via inhalation, such as this enzyme, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

Measures to eliminate or minimise risk arising from storing, handling and using the enzyme depend on the physical form and the manner in which the enzyme is used.

Further information on control measures is available in the human health risk assessment summary report (NICNAS 2017a).

53.6 References

- Basketter D, Berg N, Broekhuizen C, Fieldsend M, Kirkwood S, Kluin C, Mathieu S and Rodriguez C (2012) Enzymes in Cleaning Products: An Overview of Toxicological Properties and Risk Assessment/Management. *Reg Toxicol Pharmacol* 64: 117-123
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- HERA (2005) Human and Environmental Risk Assessment on ingredients of household cleaning products (α -amylase, cellulases and lipases). Edition 1.0, November 2005. Accessed in October 2013 at: http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on the chemical. European Union. Accessed November 2013 <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

D54 Ester alcohol

CAS RN	Chemical Name
CBI	Ester alcohol

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

54.1 Chemical use and concentration

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final drilling fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in drilling fluid at a CBI concentration.

54.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the Organisation of Economic Co-operation and Development (OECD) (OECD 2002) and the Registration, Evaluation, Authorisation and Restriction of Chemicals dossier of the chemical (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The chemical has low acute oral, dermal and inhalation toxicity, is not a skin or eye irritant, and is not a skin sensitiser.

A No-Observed-Adverse-Effect Level (NOAEL) could not be established for systemic effects in the repeated dose toxicity studies. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk, the highest dose tested in the critical study (1 000 mg/kg bw/day) is used in this risk assessment.

The chemical is neither genotoxic nor a reproductive toxicant. No data are available to determine the carcinogenic potential of the chemical.

54.3 Human exposure assessment

54.3.1 Worker exposure

Exposure of workers to the chemical is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.264) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.264 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via the transport and storage of drilling muds are negligible (NICNAS 2017a).

54.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.265) and children (Table D.266).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.265 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use			n.d.
Drinking, bathing and swimming in contaminated			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.266 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use			n.d.
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

54.4 Human health risk characterisation

54.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

54.4.2 Occupational health risks

54.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary

depending on work practices. However, given the low concentration in drilling fluids, exposure to the chemical via these fluids is of low concern for workers.

54.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 1 000 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.267).

Table D.267 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of drilling chemicals	n.d.
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection, handling of drilling muds are not calculated due to negligible human exposures (Table D.264). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

54.4.3 Public health risks

54.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

54.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.268).

Table D.268 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE)* (ADULT)	Margin of Exposure (MOE)* (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated	n.d.	n.d.

Public exposure scenario	Margin of Exposure (MOE)* (ADULT)	Margin of Exposure (MOE)* (CHILDREN)
surface water		

*n.d. – not disclosed. * For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

Based on uncertainty factors derived for this risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOE < 100 for children a potential concern cannot be ruled out from repeated exposures based on the modelled exposure scenarios. However, the MOE > 100 for adults indicates that adverse health effects are not expected.

54.4.4 Conclusions

54.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the chemical as delivered to operational sites is of low concern for workers during operations.

Exposure to the chemical via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

54.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk spill, calculated MOEs < 100 indicate that potential concern cannot be ruled out for children. However, the MOE > 100 for adults indicates that adverse health effects are not expected.

54.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

54.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical is currently not classified and does not require classification as a workplace hazardous chemical.

Risk estimates for this chemical suggest that there is low concern for acute or chronic effects to workers from the use of this chemical in coal seam gas operations. No specific risk mitigation recommendations are therefore required.

54.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for children from repeated exposure to the chemical from water contamination resulting from the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

54.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

54.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2002) Screening Information Data Set (SIDS) Screening Initial Assessment Report for the chemical. Organisation for Economic Co-operation and Development (OECD). Existing Chemicals Database. Accessed 8 November 2013 at <http://webnet.oecd.org/hpv/ui/Search.aspx>
- REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on the chemical. European Union. Accessed 8 November 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.

D55 Ethoxylated fatty acid I

CAS RN	Chemical Name
CBI	Ethoxylated fatty acid I

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

55.1 Chemical use and concentration

Ethoxylated fatty acid I is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction.

The substance is used as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluids, ethoxylated fatty acid I as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled at a CBI concentration. No information was available on the physical state of the substance. However, based on its function, concentration and the physical state of an analogous substance ethoxylated fatty acid (3) reported by industry (NICNAS 2017b), it is assumed that ethoxylated fatty acid I is delivered to site as a liquid. After incorporation, ethoxylated fatty acid I is present in hydraulic fracturing fluids at a CBI concentration.

55.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for the substance (NICNAS 2017c).

Limited toxicity information is available on ethoxylated fatty acid I. Data are available for the structurally similar alcohol ethoxylate (AE) compounds. Based on the similarity of chemical structure, composition and biotransformation of the substance and the AE class with overlapping fatty alkyl chain lengths, the use of data for the latter is appropriate to read-across for the endpoints where no data are available for the substance. Information on health hazards was sourced primarily from the Human and Environmental Risk Assessment (HERA) review of AE compounds (HERA 2009).

Based on data available for AEs, the substance is expected to have low to moderate acute oral toxicity and low dermal and inhalation toxicity. It is expected to cause skin irritation in animals and be a severe eye irritant. The analogue substance, ethoxylated fatty acid II was not found to be a skin sensitiser and it is likely that ethoxylated fatty acid I is also not a skin sensitiser.

Ethoxylated fatty acid I has not been tested for repeated dose toxicity. Reliable repeated dose oral studies for AEs indicated effects on body and organ weights in rats. A No

Observed Adverse Effect Level (NOAEL) of 50 mg/kg bw/d for systemic toxicity was determined in a 90-day study with an AE analogue based on reduced bodyweight gain, increased liver and spleen weights, and changes to clinical chemistry and haematological parameters. This NOAEL is used in this human risk assessment of ethoxylated fatty acid I.

The AEs are not genotoxic, carcinogenic, or reproductive toxicants. Based on these data, ethoxylated fatty acid I is not genotoxic, carcinogenic, or a reproductive toxicant.

55.3 Human exposure assessment

55.3.1 Worker exposure

Exposure of workers to the substance is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised substance/particulates during operations. Exposure may also occur from contact with produced water containing residual ethoxylated fatty acid I.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with substance handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (**Error! Reference source not found.**) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.269 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and			n.d.

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
maintenance (hydraulic fracturing)			
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; *E_{inh}* – Internal dose from inhalation exposure; *E_{total}* – Total internal dose from all routes; n.d. – not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

55.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosols/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to ethoxylated fatty acid I via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (**Error! Reference source not found.**) and children (**Error! Reference source not found.**).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.270 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.271 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

55.4 Human health risk characterisation

55.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

55.4.2 Occupational health risks

55.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure substance will result in adverse health effects such as skin irritation and serious eye damage. Given the concentration of the substance as delivered to operational sites, the substance in this form is of potential concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the substance via these fluids is of low concern for workers.

55.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures are systemic effects associated with reduced bodyweight gain, increased liver and spleen weights, and changes to clinical chemistry and haematological parameters. The NOAEL established for these effects is 50 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for these effects with exposures estimated for different occupational activities and combined activities (**Error! Reference source not found.**).

Table D.272 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (**Error! Reference source not found.**).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

55.4.3 Public health risks

55.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

55.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (**Error! Reference source not found.**).

Table D.273 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak–groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak–surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (**Error! Reference source not found.** and **Error! Reference source not found.**).*

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative (Tier 1) exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

55.4.4 Conclusions

55.4.4.1 Occupational health risks

The substance as delivered to operational sites is of potential concern for workers during operations based on the potential for skin irritation and serious damage to the eyes.

Exposure to the substance via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

55.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites, and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative (Tier 1) exposure modelling suggested a potential concern for adults and children for repeated exposures to surface water contaminated from a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

55.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

55.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

55.5.2 Control measures available to minimise risks to the public

55.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

55.6 References

- HERA (2009) Human and Environmental Risk Assessment on ingredients of household cleaning products (alcohol ethoxylates). Version 2, September 2009. Accessed in January 2014 at: http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

D56 Ethoxylated fatty acid II

CAS RN	Chemical Name
CBI	Ethoxylated fatty acid II

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

56.1 Chemical use and concentration

The substance is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

56.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

Ethoxylated fatty acid II is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), having a biological origin.

Information on health hazards was obtained predominantly from Cosmetic Ingredient Reviews (CIR 2003a, 2003b) and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The substance has low acute oral toxicity, is a slight skin irritant, and is not irritating to the eye at 30% but slightly irritating at 50%. Based on slight irritation at 50%, the substance is likely to be an eye irritant at 100%. The substance is not a skin sensitiser.

A No-Observed-Adverse-Effect Level (NOAEL) was not established in any of the repeat dose studies. The oral administration of the substance produced no significant effects at doses up to 5% (equivalent to 7 143 mg/kg bw/day). Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk the highest dose tested in the critical study (7 143 mg/kg bw/day) is used in this risk assessment.

The substance is not genotoxic, carcinogenic, or a developmental toxicant.

56.3 Human exposure assessment

56.3.1 Worker exposure

Exposure of workers to ethoxylated fatty acid II is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of the volatilised substance/aerosols during operations. Exposure may also occur from contact with produced water containing residual ethoxylated fatty acid II.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.274) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates including descriptions of the hydraulic fracturing process is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.274 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017b).

56.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the volatilised substance/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the substance via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.275) and children (

Table D.276).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.275 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.276 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

56.4 Human health risk characterisation

56.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

56.4.2 Occupational health risks

56.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the substance, as delivered to the site is unlikely to result in adverse health effects. Therefore, the chemical is of low concern for workers.

Acute, inadvertent exposures to the substance as delivered to operational sites are most likely during manual handling of the substance (if required) and during manipulation of equipment containing residual substance during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the substance via these fluids is of low concern for workers.

56.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the substance at any dose tested, up to 7 143 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.277).

Table D.277 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.274); n.d. – not disclosed. ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

56.4.3 Public health risks

56.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

56.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.278).

Table D.278 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.275 and

Table D.276); n.d. – not disclosed. ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the substance is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

56.4.4 Conclusions

56.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the substance as delivered to operational sites is of low concern for workers during operations. Exposure to the substance via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the substance is of low concern, for workers from repeated exposures during operations.

56.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the substance is of low concern for adults or children based on the modelled exposure scenarios.

56.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

56.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical is not currently classified and does not require classification as a workplace hazardous chemical. Risk estimates for this chemical suggest that there is low concern for acute or chronic effects to workers from the use of this chemical in coal seam gas operations. No specific risk mitigation recommendations are therefore required.

56.6 References

- CIR (2003a) Final report on the safety assessment of the substance. Cosmetic Ingredient Review Expert Panel.
- CIR (2003b) Amended safety assessment of the substance as used in cosmetics. Cosmetic Ingredient Review Expert Panel.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

REACH (2013) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on the substance. European Union. Accessed 17 September 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.

D57 Ethoxylated fatty acid III

CAS RN	Chemical Name
CBI	Ethoxylated fatty acid III

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

57.1 Chemical use and concentration

Ethoxylated fatty acid III is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction.

The substance is used as a component of hydraulic fracturing fluid formulations for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluids, ethoxylated fatty acid III as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled at a CBI concentration. No information was reported on the physical state of the substance; however, a Material Safety Data Sheet (MSDS) for the pure chemical states a melting point of 10°C, indicating that it is a liquid at room temperature.

After incorporation, ethoxylated fatty acid III is present in hydraulic fracturing fluids at a CBI concentration.

57.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for the substance (NICNAS 2017c).

Limited toxicity information is available on ethoxylated fatty acid III. Data are available for the structurally similar alcohol ethoxylate (AE) compounds. Based on the similarity of chemical structure, composition and biotransformation of the substance and the AE class with overlapping fatty alkyl chain lengths, the use of data for the latter is appropriate to read-across for the endpoints where no data are available for the substance. Information on health hazards was sourced primarily from the Human and Environmental Risk Assessment review of AE compounds (HERA 2009).

Based on data available for AEs, the substance has low to moderate acute oral toxicity and low dermal and inhalation toxicity. It causes skin irritation in animals and is a severe eye irritant. Ethoxylated fatty acid III was not found to be a skin sensitiser.

Ethoxylated fatty acid III has not been tested for repeated dose toxicity. Reliable repeated dose oral studies for AEs indicated effects on body and organ weights in rats. A No Observed Adverse Effect Level (NOAEL) of 50 mg/kg bw/d for systemic toxicity was

determined in a 90-day study with an AE analogue based on reduced bodyweight gain, increased liver and spleen weights, and changes to clinical chemistry and haematological parameters. This NOAEL is used in this human risk assessment of ethoxylated fatty acid III.

The AEs are not genotoxic or carcinogenic, or reproductive toxicants. Based on these data, ethoxylated fatty acid III is not genotoxic, carcinogenic, or a reproductive toxicant.

57.3 Human exposure assessment

57.3.1 Worker exposure

Exposure of workers to the substance is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised substance/particulates during operations. Exposure may also occur from contact with produced water containing residual ethoxylated fatty acid III.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with substance handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.279) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.279 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water transport and storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of produced water are negligible (NICNAS 2017a).

57.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of the aerosols/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to ethoxylated fatty acid III via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.280) and children (Table D.281).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.280 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak-groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

Table D.281 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak- groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are negligible for both groundwater and surface water (see NICNAS 2017a).

57.4 Human health risk characterisation

57.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

57.4.2 Occupational health risks

57.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure substance will result in adverse health effects such as skin irritation and serious eye damage. Given the concentration of the substance as delivered to operational sites, the substance in this form is of potential concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing residual chemicals during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the substance via these fluids is of low concern for workers.

57.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures are systemic effects associated with reduced bodyweight gain, increased liver and spleen weights, and changes to clinical chemistry and haematological parameters. The NOAEL established for these effects is 50 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for these effects with exposures estimated for different occupational activities and combined activities (Table D.282).

Table D.282 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.279).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

57.4.3 Public health risks

57.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

57.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.283).

Table D.283 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
<i>Accidental bulk spill during transport and surface runoff</i>		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
<i>Long-term subsurface leak from flowback and / or produced water storage pond</i>		
Combined exposure from subsurface leak–groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak–surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.280 and Table D.281).*

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures to surface water contaminated from a bulk transport spill.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative (Tier 1) exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

57.4.4 Conclusions

57.4.4.1 Occupational health risks

The substance as delivered to operational sites is of potential concern for workers for acute effects during operations based on the potential for skin irritation and serious damage to the eyes.

Exposure to the substance via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the substance is of low concern for workers from repeated exposures during operations.

57.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites, and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative (Tier 1) exposure modelling suggested a potential concern for adults and children based on repeated exposures to surface water contaminated from a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

57.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

57.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on control measures is available in the human health risk assessment summary report (NICNAS 2017a).

57.5.2 Control measures available to minimise risks to the public

57.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

57.6 References

- HERA (2009) Human and Environmental Risk Assessment on ingredients of household cleaning products (alcohol ethoxylates). Version 2, September 2009. Accessed in January 2014 at: http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

D58 Fatty acids ester

CAS RN	Chemical Name
CBI	Fatty acids ester

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

58.1 Chemical use and concentration

Fatty acids ester is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction. The substance is composed of a mixture of five fatty acid esters ranging in molecular weight from 200 to 400 Da (REACH 2013a) and is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final drilling fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a liquid at a concentration of 860 g/L (100%). After incorporation, it is present in drilling fluid at a CBI concentration.

58.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

The information on health hazards of the substance was sourced primarily from a report by NICNAS (NICNAS YEAR) and a Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier submission for the substance (REACH 2013a).

Information was also available on two of the five chemical constituents of the substance. The health hazards of Constituent 1 were sourced from an IUCLID dataset (European Commission 2013) and a REACH dossier submission for the chemical (REACH 2013b). For Constituent 2, a Cosmetics Ingredient Review safety assessment (CIR 2003) and a REACH dossier submission for the chemical (REACH 2013c) was available. Data gaps for the substance are filled by reading across data available for Constituent 1 and Constituent 2. However, noting that the substance is fully synthetic rather than being derived from natural sources, the proportions of the two constituents in the substance are not known.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Fatty acids ester demonstrates low acute oral toxicity. Based on data available for two constituents, the chemical also has low acute toxicity by dermal and inhalation routes. It is not irritating to the skin and is not a skin sensitiser. Data available for two constituents indicate that the substance is unlikely to be an eye irritant.

In an oral repeat dose toxicity test, the substance was well tolerated and a No Observed Adverse Effect Level (NOAEL) could not be established for local or systemic effects. Similarly, no NOAEL could be derived in repeat dose tests via the oral and dermal route for Constituent 1 and Constituent 2 respectively. In the critical 28-day gavage study of fatty acids ester in rats, there were no adverse effects observed at a dose of up to 1 000 mg/kg bw/day. An adjustment factor of three is applied for inadequate duration of this study, as the highest no-effect dose was derived from a 28-day study. Consequently, based on the absence of adverse effects observed, for the purposes of quantifying the health risk of the substance, the highest adjusted dose tested (333 mg/kg bw/day) is used in this risk assessment.

The substance is not genotoxic and, based on test data for a related UVCB (which contained unspecified quantities of Constituent 2) is not likely to be a developmental toxicant. This is despite a metabolite of fatty acids ester being reported to cause developmental toxicity in rats. This indicates that toxicokinetic factors are limiting any health impacts of the metabolite.

58.3 Human exposure assessment

58.3.1 Worker exposure

Exposure of workers to fatty acids ester is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of repeated worker exposures associated with mixing / blending of the substance as delivered to operational sites and equipment cleaning and maintenance with potential contact with the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.284) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.284 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.060	0.161	0.221
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds			Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

58.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the aerosolised/volatilised substance to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the substance to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the substance via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water, particularly as the substance has low volatility. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.285) and children (Table D.286).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.285 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	19.874	N/A	19.874
Bathing in contaminated surface water	Negligible*	1.18 x 10 ⁻³	1.18 x 10 ⁻³
Swimming in contaminated surface water	1.47 x 10 ⁻³	1.18 x 10 ⁻³	2.65 x 10 ⁻³
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			19.878

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.286 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	69.558	N/A	69.558
Bathing in contaminated surface water	Negligible*	2.05 x 10 ⁻³	2.05 x 10 ⁻³
Swimming in contaminated surface water	2.06 x 10 ⁻²	2.19 x 10 ⁻³	2.28 x 10 ⁻²
Combined Exposure - Drinking/bathing/swimming in contaminated surface water			69.583

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

58.4 Human health risk characterisation

58.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

58.4.2 Occupational health risks

58.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the substance is unlikely to result in adverse health effects. Therefore, the substance is of low concern for workers, even though it is delivered to operational sites as the pure substance.

Acute, inadvertent exposures are most likely during manual handling of the substance (if required) and during manipulation of equipment containing residual substance during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of drilling fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, exposure to the substance via these fluids is of low concern for workers.

58.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the substance at the highest adjusted dose tested of 333 mg/kg bw/day.

MOEs for the adverse health effects from repeated occupational exposures are calculated by comparing this highest adjusted no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.287).

Table D.287 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of drilling chemicals	1509
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.284). ** In the absence of a NOAEL, these MOEs were calculated based on the highest adjusted dose.*

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance as delivered to operational sites is of low concern for workers from repeated exposures during certain operations.

Given the low concentration of the substance in drilling fluids, repeated exposure to the substance via these fluids is of low concern for workers.

58.4.3 Public health risks

58.4.3.1 Acute health risks

Given industrial use of fatty acids ester for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

58.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the substance at the highest dose tested of 333 mg/kg bw/day. Based on this

highest adjusted no-effect dose, the MOEs were calculated for adults and children for various exposure scenarios (Table D.288).

Table D.288 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	17	5

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.285 and Table D.286). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOEs derived for repeated public exposures in the event of an accidental transport spill a potential concern cannot be ruled out for adults and children.

58.4.4 Conclusions

58.4.4.1 Occupational health risks

Given the lack of acute adverse health effects, the substance as delivered to operational sites is of low concern for workers during operations.

Calculated MOEs indicate that the substance as delivered to operational sites is of low concern for workers from repeated exposures during certain operations. Also, repeated exposure to the substance via drilling fluids is of low concern for workers.

58.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination from an accidental bulk spill, based on the MOEs a potential concern cannot be ruled out for adults and children.

58.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

58.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently not classified and does not require classification as a workplace hazardous chemical.

Risk estimates for this chemical suggest that there is low concern for acute or chronic effects to workers from the use of this chemical in coal seam gas operations. No specific risk mitigation recommendations are therefore required.

58.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for adults and children from repeated exposure to the chemical from water contamination resulting from the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

58.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

58.6 References

- European Commission (2013): European chemical Substances Information System (ESIS). IUCLID Dataset for constituent 1, European Chemicals Bureau. Accessed November 2013 at: <http://esis.jrc.ec.europa.eu/>
- CIR (2003) Final Report on the Safety Assessment of three chemicals. Cosmetic Ingredient Review Expert Panel.
- NICNAS (YEAR) Full Public Report for the substance. National Industrial Chemicals Notification and Assessment Scheme.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

REACH (2013a) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on the substance. European Union. Accessed November 2013 at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

REACH (2013b) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on Constituent 1. European Union. Accessed November 2013 at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

REACH (2013c) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier on Constituent 2. European Union. Accessed November 2013 at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.

D59 Inner salt of alkyl amines

CAS RN	Chemical Name
CBI	Inner salt of alkyl amines

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

59.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

59.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Information on health hazards was obtained predominantly from the following comprehensive reviews of the chemical: Comprehensive Ingredient Review (CIR), screening level hazard characterisation of chemicals by the United States Environmental Protection Agency (US EPA 2010), Organisation for Economic Co-operation and Development (OECD 2013) assessment of the chemical category.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The chemical has low acute oral and dermal toxicity. The chemical is a mild skin irritant at 30% and is not irritating to the skin at 15% in animals, and is an eye irritant. Cumulative skin irritation tests in humans found that the chemical is a skin irritant at 1.9% concentration. The chemical is not a skin sensitiser.

A No-Observed-Adverse-Effect Level (NOAEL) could not be established for systemic effects in the repeated dose toxicity studies at the highest dose tested of 1 000 mg/kg bw/day. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk, the highest dose tested in the critical study (1 000 mg/kg bw/day) is used in this risk assessment.

The chemical is not genotoxic or carcinogenic based on the available data. The chemical caused local effects to the dams in a developmental study, with the developmental effects considered to be secondary to maternal toxicity.

59.3 Human exposure assessment

59.3.1 Worker exposure

Exposure of workers to the chemical is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual chemical.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered, as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.289) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.289 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

59.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in waters that are known to be contaminated may be unlikely, but are possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.290) and children (Table D.291).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.290 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.291 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

59.4 Human health risk characterisation

59.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

59.4.2 Occupational health risks

59.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical will result in adverse health effects, such as eye irritation. Cumulative skin irritation tests in humans showed that the chemical is irritating in a 1.9% solution, with a median irritation time of two days, noting that the skin irritation potential was determined from occlusive patches of the chemical applied for 23 hours per day for 21 consecutive days. Thus, exposure to the chemical may result in acute adverse health effects to workers, noting the chemical is at a much higher concentration as delivered to operational sites than was examined in these studies, although workers are likely to be exposed for a much shorter period of time compared to the extended periods of exposure used in these studies.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

59.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the chemical at any dose tested, up to 1 000 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.292).

Table D.292 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)**
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.289). ** In the absence of a NOAEL, these MOEs were calculated based on the highest available dose.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

59.4.3 Public health risks

59.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

59.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.293).

Table D.293 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

*n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.290 and Table D.291). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.*

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOE < 100 derived for repeated exposures of children to contaminated groundwater/surface water from a leaking storage pond a potential concern cannot be ruled out. Moreover, the MOEs > 100 for adults and children for the other exposure scenarios indicate a low concern.

59.4.4 Conclusions

59.4.4.1 Occupational health risks

The chemical as delivered to operational sites is of potential concern for workers during operations based on the potential for eye and skin irritation.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical as delivered to operational sites is of low concern for workers from repeated exposures during operations. Also, repeated exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

59.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults and children based on certain modelled exposure scenarios. For the exposure scenario of a leaking storage pond, based on the MOE for repeated exposure of children to groundwater/surface water a potential concern cannot be ruled out.

59.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

59.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical indicate a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on control measures is available in the human health risk assessment summary report (NICNAS 2017b).

59.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for children from repeated exposure to the chemical from water contamination resulting from some of the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

59.5.2.1 Storage of flowback and / or produced water

For chemical for which risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

59.6 References

- CIR (2003) Cosmetic Ingredient Review Expert Panel Final Report on the Safety Assessment of the chemical.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2013) Screening Information Data Set (SIDS) Initial Assessment Report for chemical category. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database. Accessed 30 May 2013 at <http://webnet.oecd.org/hpv/ui/Search.aspx>
- US EPA (2010) Screening-level hazard characterisation: chemical category. United States Environmental Protection (US EPA) Agency Hazard Characterisation Document. Accessed June 2010 at <http://www.epa.gov/> .

D60 Organic acid salt

CAS RN	Chemical Name
CBI	Organic acid salt

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

60.1 Chemical use and concentration

The chemical is used as a component of a drilling fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final drilling fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in drilling fluid at a CBI concentration.

60.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

No information on the physical properties or health hazards of the chemical is available from the published literature. However, peer reviewed data for related chemicals were available in an Organisation for Economic Co-operation and Development Screening Information Data Set Initial Assessment Report (OECD 2007a,2007b) for the chemical category alkyl sulfates, alkane sulfonates and α -olefin sulfonates. In the absence of data specific for the chemical, data were read-across from these related chemicals.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Based on available studies of alkyl sulfates of longer chain length, organic acid salt is of low acute oral and dermal toxicity. In general, alkyl sulfates are corrosive to the skin in concentrated form. Accordingly, organic acid salt is considered to be corrosive to the skin and a severe eye irritant. It is not considered to be a skin sensitiser.

In repeat dose toxicity studies of alkyl sulfates, the liver appeared to be the primary target organ, with increases in liver weight, cellular enlargement and elevated levels of liver enzymes, and changes in other clinical chemistry parameters observed consistently. For defined chain length alkyl sulfates, and by read-across to organic acid salt, an oral No-Observed-Adverse-Effect Level (NOAEL) for repeat dose toxicity was established at 230 mg/kg bw/day from a 13-week rat feeding study on an analogue alkyl sulphate. This NOAEL is used in this human health risk assessment.

Genotoxicity testing *in vitro* and *in vivo* did not suggest alkyl sulfates possess genotoxic potential. In addition, available oral studies for alkyl sulfates and dermal studies for appropriate α -olefin sulfonates did not report evidence of carcinogenicity. Similarly, organic acid salt is not considered a genotoxin or carcinogen. Available studies do not show evidence of fertility or developmental toxic effects in the absence of maternal toxicity.

60.3 Human exposure assessment

60.3.1 Worker exposure

Exposure of workers to the chemical is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosols during operations. Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.294) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.294 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

60.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of volatilised chemical to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.295) and children (Table D.296).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.295 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

Table D.296 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

60.4 Human health risk characterisation

60.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

60.4.2 Occupational health risks

60.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site will result in adverse health effects such as serious damage to the skin and eyes.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of drilling fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, exposure to the chemical via these fluids is of low concern for workers.

60.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effects for repeated exposures to the chemical were cellular enlargement and elevated levels of liver enzymes and changes in other clinical chemistry parameters. The NOAEL established for this effect is 230 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.297).

Table D.297 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	n.d.
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection and handling of drilling muds are not calculated due to negligible human exposures (Table D.294).*

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

60.4.3 Public health risks

60.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

60.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.298).

Table D.298 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults and children from repeated exposures based on the modelled exposure scenarios.

60.4.4 Conclusions

60.4.4.1 Occupational health risks

The concentrated form of the chemical as delivered to operational sites is of potential concern for workers during operations, based on the potential for serious damage to the skin and eyes.

Exposure to the chemical via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

60.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults and children based on the modelled exposure scenarios.

60.5 Risk mitigation measures

60.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017a), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals.

Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

60.6 References

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- OECD (2007a) Screening Information Data Set (SIDS) Initial Assessment Profile for SIAM 25. Alkyl Sulfates, Alkane Sulfonates and α -Olefin Sulfonates.
- OECD (2007b) Screening Information Data Set (SIDS) Initial Assessment Report for SIAM 25. Alkyl Sulfates, Alkane Sulfonates and α -Olefin Sulfonates.

D61 Organic sulfate

CAS RN	Chemical Name
CBI	Organic sulfate

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

61.1 Chemical use and concentration

Organic sulfate is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction and comprises a range of carbon chain lengths and ethoxylated units. The substance is used as a component of drilling fluid formulations for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final drilling fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a liquid. In the absence of reported information on the concentrations of the substance, default concentrations of 300 g/L (30%) as transported and 0.85 g/L (0.085%) in the drilling fluid are assumed (DMITRE 2014).

61.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017c).

Toxicological information on the specific substance is not available. However, toxicological information for alcohol ethoxysulphates with appropriate carbon chain lengths, counter ions and number of ethoxy units is available and used to read-across for toxicity of the substance (HERA 2003 and other confidential sources).

Based on studies with closely related compounds, the substance is considered to have low acute oral and dermal toxicity, and is expected to be a skin irritant and severe eye irritant, but not a skin sensitiser.

No systemic treatment-related effects were observed in repeat dose oral studies with structurally related compounds up to a dose of 250 mg/kg bw/day. Based on the absence of adverse effects observed in repeat dose toxicity studies, for the purposes of quantifying the health risk the highest dose tested in the critical study (250 mg/kg bw/day) will be taken through to the risk assessment.

Based on a lack of effects seen with alcohol ethoxysulphates of similar carbon chain lengths, the substance is not considered to be genotoxic, carcinogenic or toxic to reproduction or development.

61.3 Human exposure assessment

61.3.1 Worker exposure

Exposure of workers to the substance is possible via inadvertent spills and leaks, especially during any required manual handling, and emissions of its aerosols during operations. Exposure may also occur from contact with produced water containing the residual substance.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the substance as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance with handling of the substance as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.299) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.299 Internal doses resulting from substance exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	0.009	0.067	0.076
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	0.0005	0.0007	0.001
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			0.081
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are regarded as negligible. Similarly, repeated occupational exposures to the chemical via transport and storage of drilling muds are negligible (NICNAS 2017a).

61.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming) and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas drilling operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of aerosolised substance to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of chemicals to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the substance via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.300) and children (Table D.301).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a).

Table D.300 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	10.017	N/A	10.017
Bathing in contaminated surface water	Negligible*	2.97 x 10 ⁻⁴	2.97 x 10 ⁻⁴
Swimming in contaminated surface water	7.43 x 10 ⁻⁴	2.97 x 10 ⁻⁴	1.04 x 10 ⁻³
Combined exposure from bulk spill – surface water use			10.018
Drinking, bathing and swimming in contaminated			

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

Table D.301 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	35.060	N/A	35.060
Bathing in contaminated surface water	Negligible*	5.16 x 10 ⁻⁴	5.16 x 10 ⁻⁴
Swimming in contaminated surface water	1.04 x 10 ⁻²	5.52 x 10 ⁻⁴	1.10 x 10 ⁻²
Combined exposure from bulk spill – surface water use			35.071
Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route. * Oral exposures associated with bathing are calculated to be negligible (see NICNAS 2017a).

61.4 Human health risk characterisation

61.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

61.4.2 Occupational health risks

61.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the substance (assumed to be 300 g/L, 30%), as delivered to the site, will result in adverse health effects, such as skin and eye irritation.

Acute, inadvertent exposures to the substance as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual substance during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of drilling fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids (assumed to be 0.85 g/L, 0.09%), exposure to the substance via these fluids is of low concern for workers.

61.4.2.2 Long-term health risks

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the substance at any dose tested, up to 250 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing this highest no-effect dose with exposures estimated for different occupational activities and combined activities (Table D.302).

Table D.302 Margins of Exposure calculated for different occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	3 300
Cleaning and maintenance (drilling)	2.0 x 10 ⁵
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	3 250

* MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.299).

Based on uncertainty factors derived for this risk characterisation, these MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

61.4.3 Public health risks

61.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

61.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

From the hazard characterisation, there are no adverse effects observed from repeated exposures to the substance at any dose tested, up to 250 mg/kg bw/day.

MOEs for adverse health effects (Table D.355) were calculated for adults and children by comparing the highest no-effect dose with exposures estimated for various scenarios outlined in Table D.300 and Table D.301.

Table D.303 Margins of Exposure calculated for the drillingpublic exposure scenario

Public exposure scenario*	Margin of Exposure (MOE)** (ADULT)	Margin of Exposure (MOE)** (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	25	7

* MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.300 and Table D.301). ** For this chemical, the highest dose tested did not result in adverse effects. However, the dose at which adverse effects may arise has not been defined, so the MOE may (or may not) be higher than the calculated MOE. Further data would resolve whether or not this chemical is of concern.

In light of the default uncertainty factors used in the risk characterisation, conservative assumptions within the exposure modelling, toxicological studies that did not identify a dose of the chemical associated with adverse effects and the MOEs a potential concern cannot be ruled out for adults and children.

61.4.4 Conclusions

61.4.4.1 Occupational health risks

The concentrated form of the substance as delivered to operational sites is of potential concern for workers during operations based on the potential for skin and eye irritation.

Exposure to the substance via drilling fluids or via produced water is of low concern for workers.

Calculated MOEs indicate that the substance is of low concern for workers during operations.

61.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, based on the MOEs a potential concern cannot be ruled out for adults and children.

61.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

61.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Information on legislated obligations and control measures is available in the human health risk assessment summary report (NICNAS 2017a).

61.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for adults and children from repeated exposure to the chemical from water contamination resulting from the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

61.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

61.6 References

- DMITRE (2014) Department of Manufacturing, Innovation Trade, Resources and Energy, South Australia. Accessed at:
http://www.petroleum.pir.sa.gov.au/prospectivity/basin_and_province_information/unconventional_gas/frequently_asked_questions.
- HERA (2003) Human and Environmental Risk Assessment on ingredients of household cleaning products (Alcohol Ethoxysulphates). January 2003. Accessed in February 2014 at: http://www.heraproject.com/files/38-F-Hera_Bridging_document_28.10.05.pdf.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals

Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

D62 Polyamine

CAS RN	Chemical Name
CBI	Polyamine

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

62.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI.

Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a solid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

62.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017c).

Only limited data are available for the adverse effects on human health of polyamine as used in the coal seam gas extraction process.

Information on health hazards was sourced primarily from the US National Library of Medicine (US National Library of Medicine 2014) and the industry submissions to the classification and labelling inventory for the pre-registered substance under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH 2014).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Polyamine as used for coal seam gas extraction is likely to be a high molecular weight polymer in solid form. The polymer is highly cationic. No data were available for levels of residual monomer, and so the extent to which toxicity of the polymer is related to, and can be predicted by, the presence of hazardous monomer is not known.

Limited acute toxicity data and classification and labelling proposals in the European Union (EU) for polyamine indicate that the polymer may be acutely toxic via the oral route. No data were available for dermal or inhalation toxicity. As a high molecular weight solid, dermal absorption is likely to be low and therefore dermal toxicity is not expected. However, reports of acute oral toxicity imply some oral absorption if toxicity is not due purely to local effects.

As suggested by the cationic nature of the polymer and classification and labelling proposals in the EU, polyamine is likely to be a skin, eye and respiratory irritant and a skin sensitiser.

No repeat dose toxicity studies were available.

Polyamine is genotoxic *in vitro*. The extent to which the polymer is genotoxic *in vivo* is not known.

62.3 Human exposure assessment

62.3.1 Worker exposure

Exposure of workers to polyamine is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of aerosolised chemical/particulates during operations. Exposure may also occur from contact with produced water containing residual polyamine.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling is used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities.

The total internal human dose is estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017a). However, in the case of polyamine, key physical property data required to calculate the dermal and inhalation absorption rates are not available and therefore the internal human dose via the two routes cannot be estimated.

62.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreational uses (e.g. swimming) and ambient air.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of aerosolised chemical/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

Moreover, as discussed in 'Worker Exposure' above, key physical property data required to calculate the oral and dermal absorption rates are not available for polyamine, and therefore the resulting internal human doses cannot be estimated.

62.4 Human health risk characterisation

Limited data concerning physical properties, acute toxicity, repeat dose toxicity, genotoxicity, carcinogenicity and reproductive toxicity impact on the ability of NICNAS to undertake a more scientifically robust risk assessment. Nonetheless, based on the data that are available, NICNAS has assessed the risks posed by polyamine in this section.

62.4.1 Occupational health risks

62.4.1.1 Acute health risks

Health effects information indicates that acute exposure to the chemical as delivered to the site may result in adverse health effects, such as skin, eye and respiratory irritation and skin sensitisation. Although data are currently insufficient to support a hazard classification for the chemical, the cationic nature of the polymer and classification and labelling proposals in the EU suggest that such acute effects are possible.

Acute, inadvertent exposures are most likely during manual handling of the chemical (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to polyamine in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, acute exposure to the chemical via these fluids is of low concern for workers.

62.4.1.2 Long-term health risks

There are no repeat dose studies available for the chemical and no estimates of total internal human doses from repeated occupational exposures. Therefore, it is not possible to quantify the level of risk for workers for repeated occupational exposures for the modelled scenarios. Due to a lack of information on health effects, the chemical is regarded as of potential concern for workers for the modelled exposure scenarios.

62.4.2 Public health risks

62.4.2.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

62.4.2.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

There are no repeated dose studies available for the chemical and no estimates of total internal human dose from repeated exposures. Therefore, it is not possible to quantify the level of concern for adults or children from repeated exposures based on the modelled scenarios. Due to a lack of information on health effects, the chemical is regarded as of potential concern for the public from repeated exposures.

62.4.3 Conclusions

Based on the data that are available, NICNAS has assessed the risks posed by polyamine. Limited data concerning physical properties, acute toxicity and chronic toxicity preclude the conduct of a more scientifically robust risk assessment.

62.4.3.1 Occupational health risks

The chemical is of potential concern for workers during operations based on indirect evidence suggesting the potential for skin, eye and respiratory irritation and skin sensitisation from acute exposures. Based on a lack of health effects information, the chemical is regarded as of potential concern for repeated occupational exposures.

62.4.3.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, it is not possible to quantify the level of concern for adults or children for the modelled scenarios. However, based on the lack of health effects information, the chemical is regarded as of potential concern for the public from repeated exposures.

62.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

62.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is not currently classified as a workplace hazardous chemical. Moreover, available data were insufficient to support a hazard classification for the chemical.

However, risk estimates for this chemical suggest a potential concern for workers.

Persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on control measures is available in the human health risk assessment summary report (NICNAS 2017a).

62.5.2 Control measures available to minimise risks to the public

It is not possible to draw definitive conclusions regarding the level of concern for adverse systemic health effects for adults and children from repeated exposure to the chemical from water contamination resulting from the modelled exposure scenarios.

Conservatively, it is prudent to note the following generic measures to decrease the potential for environmental contamination and risks to human health from use of this chemical.

62.5.2.1 Transport

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

62.5.2.2 Storage of flowback and / or produced water

For chemicals for which risk estimates from conservative exposure modelling suggest a potential concern from contamination of shallow groundwater from a leaking storage pond, the following risk mitigation measures are available (NICNAS 2017a).

- Ensure flowback water is appropriately treated prior to its disposal or recycling and not subject to long-term storage in surface pits/ponds.
- Ensure that appropriate lining of pits/ponds for flowback and / or produced water storage is used to minimise leaks.
- Monitor the integrity of the storage pits/ponds (e.g. routine inspection activities) and install monitoring measures (e.g. leak detection technology) to minimise the likelihood of leaks to soil and shallow groundwater which exceed design limits.

If site-specific assessments confirm a potential public health concern, then the chemical could be included in a groundwater monitoring program. Where possible, baseline studies conducted prior to coal seam gas developments would enhance the utility of such a program.

62.6 References

- US National Library of Medicine (2014) ChemIDplus Advanced. Accessed February 2014 at <http://chem.sis.nlm.nih.gov/chemidplus/>
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification

and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

REACH (2014) Submissions to the classification and labelling inventory for the pre-registered substance under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) program. European Union. Accessed February 2014 at <http://clp-inventory.echa.europa.eu/SummaryOfClassAndLabelling.aspx> .

D63 Polymer with substituted alkylacrylamide salt

CAS RN	Chemical Name
CBI	Polymer with substituted alkylacrylamide salt

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

63.1 Chemical use and concentration

The chemical is considered a residual, unreacted component in a polymer (chemical identity disclosed to NICNAS), which is the main component of a product used in drilling fluid formulation for coal seam gas extraction.

The document from here on refers to Polymer with substituted alkylacrylamide salt as 'residual component'.

Prior to incorporation into the final drilling fluid, the residual component as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as liquid with CBI concentration. After incorporation into the drilling fluid, the residual component is present in drilling fluid at a CBI concentration.

63.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017a). This risk assessment report is only concerned with the human health risks arising from the residual component.

Information on health hazards was obtained predominantly from the Agency for Toxic Substances and Disease Registry (ATSDR 2013), National Industrial Chemicals Notification and Assessment Scheme (NICNAS YEAR), United States Environmental Protection Agency Integrated Risk Information System (US EPA 2013), International Agency for Research on Cancer (IARC 2013) and the National Toxicology Program (NTP 2013).

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The residual component has moderate acute oral and dermal toxicity, is irritating to the skin and eyes, and is a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment of repeated oral exposure to the chemical is 0.2 mg/kg bw/day based on neurotoxic effects at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 1 mg/kg bw/day.

The residual component is genotoxic, carcinogenic (NOAEL = 1.32 and 0.44 mg/kg bw/day in males and females, respectively), and toxic to fertility (NOAEL = 2 mg/kg bw/day).

63.3 Human exposure assessment

63.3.1 Worker exposure

Exposure of workers to the residual component is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of the volatilised chemical/particulates during operations. Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with handling of the residual component incidental to handling the product for particular coal seam gas workplace activities. Exposures were calculated for incidental mixing / blending of the residual component in the product as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with incidental handling of the residual component as an unintended component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.304) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the drilling process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.304 Internal doses resulting from chemical exposures associated with drilling occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of drilling chemicals	n.d.	n.d.	n.d.
Injection of drilling chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (drilling)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)			n.d.
Transport and storage of drilling muds	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of the mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via the transport and storage of drilling muds are negligible (NICNAS 2017a).

63.3.2 Public exposure

The public may be exposed to the residual component via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air. Consequently, for public health risk characterisation, exposures to the residual component from coal seam gas drilling operations via oral, dermal and inhalational routes are considered. The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- emissions of the volatilised residual component/particulates containing the residual component to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the residual component to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the residual component via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.305) and children (

Table D.306).

Further detail on the derivation of public exposure estimates including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.305 Internal doses for ADULTS associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
use Drinking, bathing and swimming in contaminated surface water			

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

Table D.306 Internal doses for CHILDREN associated with drilling public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} - Internal dose from dermal exposure; E_{total} - Total internal dose from all routes. N/A - not an applicable exposure route; n.d. - not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a).

63.4 Human health risk characterisation

63.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

63.4.2 Occupational health risks

63.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the residual component as the pure chemical will result in adverse health effects such as acute dermal toxicity, skin and eye irritation, and skin sensitisation. However, given the concentration of the chemical as delivered to operational sites is less than the default concentration cut-offs for the above

acute adverse health effects, the residual component in this form is of low concern for workers.

Acute, inadvertent exposures to the residual component in the product as delivered to operational sites are most likely during manual handling of the product (if required) and during manipulation of equipment containing the residual component during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The residual component occurs in a product that is a component of drilling fluids. Similarly to exposures to the residual component in the product as delivered to operational sites, levels of exposure to the residual component in these fluids will vary depending on work practices. However, given the low concentration in drilling fluids, exposure to the residual component via these fluids is of low concern for workers.

63.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect from repeated exposures to the residual component is neurotoxicity. The NOAEL established for this effect is 0.2 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.307).

Table D.307 Margins of Exposure calculated for drilling occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of drilling chemicals	n.d.
Cleaning and maintenance (drilling)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (drilling)	n.d.

*n.d. – not disclosed. * MOEs for transport/storage, injection, handling of drilling muds are not calculated due to negligible human exposures (Table D.304).*

The corresponding MOEs for carcinogenicity (derived from NOAELs which are 2.2 - 6.6 times larger than the neurotoxicity NOAEL) and toxicity to fertility (derived from a NOAEL which is ten times larger than the neurotoxicity NOAEL) will be correspondingly greater than the MOEs for neurotoxicity.

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the residual component in the product is of low concern for workers from repeated exposures during certain operations.

63.4.3 Public health risks

63.4.3.1 Acute health risks

Given industrial use of the product for coal seam gas extraction, the public is unlikely to come into contact with the residual component present in the product as delivered to operational sites. Therefore, the residual component in this form is of low concern for the public.

63.4.3.2 Long-term health risks

The public is most likely to come into contact with the residual component via environmental contamination of water used for drinking, bathing and recreational uses. Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.308).

Table D.308 Margins of Exposure calculated for the drilling public exposure scenario

Public exposure scenario	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
<i>Accidental bulk spill during transport and surface runoff</i>		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for adults and children from repeated exposures based on the modelled exposure scenarios.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative (Tier 1) exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of chemicals (NICNAS 2017a). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

63.4.4 Conclusions

63.4.4.1 Occupational health risks

The residual component in the product as delivered to operational sites is of low concern for workers.

Exposure to the residual component via drilling fluids is of low concern for workers.

Calculated MOEs indicate that the residual component in the product is of low concern for workers from repeated exposures during operations.

63.4.4.2 Public health risks

The public is unlikely to come into contact with the residual component in the product as delivered to operational sites, and so the residual component in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs are suggestive of a potential concern for adults and children from repeated exposures via environmental contamination from a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

63.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

63.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

For chemicals with serious health effects via inhalation, such as this chemical, if site-specific risk assessments of occupational health risks indicate a concern, personal monitoring of workers should be conducted to determine the effectiveness of risk mitigation measures.

63.5.2 Control measures available to minimise risks to the public

63.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

63.6 References

ATSDR (2013) Toxicological profile for the chemical. Agency for Toxic Substances and Disease Registry (ATSDR), United States Department of Health and Human Services. Accessed 23 October 2013 at <http://www.atsdr.cdc.gov/>

IARC (2013) International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans. World Health Organisation, Lyon.

- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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- NICNAS (YEAR) Chemical Assessment Report. National Industrial Chemicals Notification and Assessment Scheme, Sydney.
- NTP (2013) Technical report on the toxicology and carcinogenesis studies of the chemical in F344 / N rats and B6C3F1 mice (feed and drinking water studies). National Toxicology Program (NTP), United States Department of Health and Human Services. Accessed 23 October 2013 at <http://ntp.niehs.nih.gov/>
- US EPA (2013) Toxicological review of the chemical. In support of Summary Information on the Integrated Risk Information System (IRIS). United States Environmental Protection Agency,(US EPA) Bathington DC. Accessed 23 October 2013 at <http://www.epa.gov/iris/> .

D64 Quaternary amine

CAS RN	Chemical Name
CBI	Quaternary amine

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

64.1 Chemical use and concentration

The chemical is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is CBI. Prior to incorporation into the final hydraulic fracturing fluid, the chemical as reported in the coal seam gas industry survey (NICNAS 2017c) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

64.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this chemical (NICNAS 2017a).

Information on health hazard was obtained predominantly from the Organisation of Economic Co-operation and Development (OECD 2013). This chemical was assessed as part of a group assessment.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

The chemical has low to moderate acute oral and inhalation toxicity and low acute dermal toxicity, is corrosive to the skin and eyes, and is a respiratory tract irritant.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment of the chemical is 40 mg/kg bw/day based on systemic effects at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 200 mg/kg bw/day.

The chemical is not genotoxic or carcinogenic, and is not a reproductive toxicant.

64.3 Human exposure assessment

64.3.1 Worker exposure

Exposure of workers to quaternary amine is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual chemical and / or its salts.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.309) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.309 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)			n.d.
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

64.3.2 Public exposure

The public may be exposed to the chemical via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the chemical from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/particulates to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.310) and children (

Table D.311).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.310 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.311 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use			n.d.

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Drinking, bathing and swimming in contaminated surface water			
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

64.4 Human health risk characterisation

64.4.1 Uncertainty factors

For this risk assessment, using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

64.4.2 Occupational health risks

64.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure chemical or a concentrated solution will result in adverse health effects such as acute inhalation toxicity, and skin, eye and respiratory irritation. However, given the concentration of the chemical as delivered to operational sites is less than the default concentration cut-offs for the above acute adverse health effects, the chemical in this form is of low concern for workers.

Acute, inadvertent exposures to the chemical as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The chemical is a component of hydraulic fracturing fluids. Similarly to exposures to the chemical as delivered to operational sites, levels of exposure to the chemical in these fluids will vary depending on work practices. However, given the even lower concentration in hydraulic fracturing fluids, exposure to the chemical via these fluids is of low concern for workers.

64.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) health effect for repeated exposures to the chemical is systemic toxicity. The NOAEL established for this effect is 40 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.312).

Table D.312 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.309).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the chemical is of low concern for workers from repeated exposures during certain operations.

64.4.3 Public health risks

64.4.3.1 Acute health risks

Given industrial use of the chemical for coal seam gas extraction, the public is unlikely to come into contact with the chemical as delivered to operational sites. Therefore, the chemical in this form is of low concern for the public.

64.4.3.2 Long-term health risks

The public is most likely to come into contact with the chemical via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.313).

Table D.313 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.310 and

Table D.311).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs indicate that the chemical is of low concern for adults or children from repeated exposures based on the modelled exposure scenarios.

64.4.4 Conclusions

64.4.4.1 Occupational health risks

Given the low concentration of the chemical as delivered to operational sites, the chemical is of low concern for workers despite its known acute health hazards.

Exposure to the chemical via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the chemical is of low concern for workers from repeated exposures during operations.

64.4.4.2 Public health risks

The public is unlikely to come into contact with the chemical as delivered to operational sites and so the chemical in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs indicate that the chemical is of low concern for adults or children based on the modelled exposure scenarios.

64.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

64.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical is currently classified as a workplace hazardous chemical.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Further information on these legislated obligations is available in the human health risk assessment summary report (NICNAS 2017a).

64.5.2 Control measures available to minimise risks to the public

64.5.2.1 Atmospheric monitoring

As noted in the hazard assessment report (NICNAS 2017c), this chemical is volatile i.e. with a vapour pressure ≥ 0.5 kPa at standard test temperatures (ECHA 2012) and has known adverse health hazards. For such chemicals, where there is increased potential for transport via ambient air, the following risk mitigation measures are available.

The potential for public exposures via ambient air emissions from coal seam gas developments could be assessed. If site-specific assessments indicate a potential for public exposures, the chemical could be included in an ambient air monitoring program. Where possible, baseline studies undertaken before, as well as during and after coal seam gas operations would enhance the utility of such a program.

64.6 References

- ECHA (2012) Guidance on information requirements and chemical safety assessment. Chapter R.14: Occupational exposure estimation Version 2.1 November 2012. European Chemicals Agency
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
- NICNAS (2017b) Identification of chemicals associated with coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS (2017c) Human health hazards of chemicals used in coal seam gas extraction in Australia, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

OECD Screening Information Data Set (SIDS) Initial Assessment Report. Organisation for Economic Co-operation and Development (OECD) Existing Chemicals Database. Accessed 1 August 2013 at <http://webnet.oecd.org/hpv/ui/Search.aspx>

D65 Terpenes and terpenoids

CAS RN	Chemical Name
CBI	Terpenes and terpenoids

CBI – confidential business information

Confidentiality from public disclosure was claimed for the chemical name and Chemical Abstracts Service (CAS) number of this chemical. Therefore, in this publicly available version of the risk assessment report, the chemical is listed by a generic name and its CAS Number has been omitted. Also, some of the data provided to NICNAS and used in the risk assessment for this chemical were confidential business information (CBI).

65.1 Chemical use and concentration

Terpenes and terpenoids is used as a component of a hydraulic fracturing fluid formulation for coal seam gas extraction. Its function within these fluids is not specified. Terpenes and terpenoids is considered as a substance of unknown or variable composition, complex reaction products or biological materials (UVCB), being a complex product of a chemical reaction. The substance is composed of known quantities of monoterpene hydrocarbons, consisting of Constituent 1 (and two isomers), Constituent 2, Constituent 3 and other terpene hydrocarbons (US EPA 2013).

Prior to incorporation into the final hydraulic fracturing fluid, the substance as reported in the coal seam gas industry survey (NICNAS 2017b) is transported, stored and handled as a liquid at a CBI concentration. After incorporation, it is present in hydraulic fracturing fluid at a CBI concentration.

65.2 Critical health effects

Adverse effects on human health are characterised in detail in a separate hazard assessment available for this substance (NICNAS 2017a).

Information on health hazards was obtained predominantly from the following comprehensive reviews: US EPA (US EPA 2013), Registration, Evaluation, Authorisation and Restriction of Chemicals dossier submission for the substance (REACH 2013), and a report by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS YEAR). Data gaps for the substance are read-across from data available for the isomer of Constituent 1, and Constituent 2 multiconstituent.

The critical adverse health effects from the NICNAS hazard assessment are summarised below.

Terpenes and terpenoids, has low acute oral and dermal toxicity, and is a skin irritant. Based on reading across data available for Constituent 2 multiconstituent, the substance is an eye irritant and a skin sensitiser.

The most appropriate No-Observed-Adverse-Effect Level (NOAEL) for risk assessment is 600 mg/kg bw/day based on a study on one of the isomers of Constituent 1, which resulted in decreased bodyweight at the Lowest-Observed-Adverse-Effect Level (LOAEL) of 1 200 mg/kg bw/day. This NOAEL will be applied to terpenes and terpenoids.

The substance is not genotoxic or carcinogenic based on data available for one of the isomers of Constituent 1, is not toxic to fertility based on data available for Constituent 2 multiconstituent, and is not a developmental toxicant based on available data for one of the isomers of Constituent 1.

65.3 Human exposure assessment

65.3.1 Worker exposure

Exposure of workers to the substance is possible via inadvertent spills and leaks, especially during any required manual handling, and / or emissions of volatilised chemicals/aerosols during operations. Exposure may also occur from contact with produced water containing residual substance.

Consequently, for occupational health risk characterisation, worker exposures via dermal and inhalational routes are considered for particular operational activities. Oral exposures are not considered as it is assumed that exposures via this route are negligible due to effective, easily implemented occupational hygiene measures.

In the absence of workplace monitoring data, modelling was used to derive daily estimates of exposures associated with chemical handling for particular coal seam gas workplace activities. Exposures were calculated for mixing / blending of the chemical as delivered to operational sites. Exposures were also calculated for equipment cleaning and maintenance, with handling of the chemical as a component of formulated fluids. Finally, exposures were calculated for the combined activities - mixing / blending plus cleaning and maintenance activities.

The total internal human dose (Table D.314) was estimated using exposure modelling and dermal and inhalation absorption rates determined from the hazard characterisation. Further detail on the derivation of exposure estimates, including descriptions of the hydraulic fracturing process, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.314 Internal doses resulting from chemical exposures associated with hydraulic fracturing occupational activities

Occupational activity	E _{derm} (mg/kg bw/day)	E _{inh} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Transport and storage	Negligible*	Negligible*	Negligible*
Mixing/blending of hydraulic fracturing chemicals	n.d.	n.d.	n.d.
Injection of hydraulic fracturing chemicals	Negligible*	Negligible*	Negligible*
Cleaning and maintenance (hydraulic fracturing)	n.d.	n.d.	n.d.
Combined exposure Mixing/blending and cleaning and			n.d.

Occupational activity	E_{derm} (mg/kg bw/day)	E_{inh} (mg/kg bw/day)	E_{total} (mg/kg bw/day)
maintenance (hydraulic fracturing)			
Produced water storage	Negligible*	Negligible*	Negligible*

E_{derm} - Internal dose from dermal exposure; E_{inh} - Internal dose from inhalation exposure; E_{total} - Total internal dose from all routes; n.d. - not disclosed. * In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible. Similarly, repeated occupational exposures to the chemical via produced water storage are negligible (NICNAS 2017a).

65.3.2 Public exposure

The public may be exposed to the substance via environmental contamination of water used for drinking, bathing and recreation (e.g. swimming), and ambient air.

Consequently, for public health risk characterisation, exposures to the substance from coal seam gas hydraulic fracturing operations via oral, dermal and inhalational routes are considered.

The following scenarios for environmental contamination and public exposures are considered:

- a bulk spill during transport and run-off to surface water used for drinking, bathing and recreation (swimming)
- a bulk spill from overflow from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- a long-term subsurface leak from a coal seam gas flowback and / or produced water storage pond and migration to groundwater used for drinking and bathing and to surface water used for recreation (swimming)
- emissions of volatilised chemicals/aerosols to ambient air from operations.

Drinking, bathing and swimming in known contaminated waters may be unlikely, but is possible in cases where individuals are not aware of the contamination, or when contamination is known but impacts are underestimated. Therefore, public exposure scenarios assume exposure to contaminated water.

Although emissions of the chemical to air are possible during operations or from surface spills or open water bodies, there is no monitoring information available for levels in ambient air. Also, exposures of the public to the chemical via ambient air are difficult to estimate due to extreme variability in atmospheric transport. In contrast to occupational exposures, public exposures via ambient air are likely to be low compared to exposures via water. Consequently, for the purposes of public risk characterisation, exposures via ambient air are not examined further.

For the different public exposure scenarios, conservative (Tier 1) exposure modelling was used to derive predicted environmental concentrations (PECs) for groundwater and surface water. The total internal human dose was then estimated using these PECs, frequencies of exposure to groundwater and surface water and oral and dermal absorption rates determined from the hazard characterisation. Separate internal doses were derived for adults (Table D.315) and children (

Table D.316).

Further detail on the derivation of public exposure estimates, including the models, the geological / hydrogeological parameter inputs and modelling assumptions, is available in the exposure assessment section of the final human health risk assessment report for coal seam gas chemicals (NICNAS 2017b).

Table D.315 Internal doses for ADULTS associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

Table D.316 Internal doses for CHILDREN associated with hydraulic fracturing public exposure scenarios

Public exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	E _{total} (mg/kg bw/day)
Accidental bulk spill during transport and surface runoff			
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water			n.d.
Bulk spill from flowback and / or produced water storage pond			
Bulk spill from flowback and / or produced water storage pond	Negligible**	Negligible**	Negligible**
Long-term subsurface leak from flowback and / or produced water storage pond			
Drinking contaminated groundwater	n.d.	N/A	n.d.
Bathing in contaminated groundwater	Negligible*	n.d.	n.d.
Drinking contaminated surface water	n.d.	N/A	n.d.
Bathing in contaminated surface water	Negligible*	n.d.	n.d.
Swimming in contaminated surface water	n.d.	n.d.	n.d.
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water			n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water			n.d.

E_{oral} - Internal dose from oral exposure; E_{derm} – Internal dose from dermal exposure; E_{total} – Total internal dose from all routes. N/A – not an applicable exposure route; n.d. – not disclosed. * Oral exposures associated with bathing are negligible (NICNAS 2017a). ** PECs derived for this scenario are calculated to be negligible for both groundwater and surface water (NICNAS 2017a).

65.4 Human health risk characterisation

65.4.1 Uncertainty factors

For this risk assessment using a Margin of Exposure (MOE) approach, conservative default uncertainty factors for intra- and inter-species variability are assumed to be 10 each. No additional uncertainty factors are deemed necessary to account for data inadequacies, the

nature of adverse health effects or the affected population e.g. adults versus children. Consequently, in the risk characterisation, an MOE of less than 100 is considered a concern.

65.4.2 Occupational health risks

65.4.2.1 Acute health risks

Health effects information indicates that acute exposure to the pure substance will result in adverse health effects, such as skin irritation and skin sensitisation. Given the concentration of the substance as delivered to operational sites, the chemical in this form is of potential concern for workers.

Acute, inadvertent exposures to the substance as delivered to operational sites are most likely during manual handling of chemicals (if required) and during manipulation of equipment containing the residual chemical during operations, cleaning and maintenance and during clean-up of spills. Levels of exposure will vary depending on the work practices employed.

The substance is a component of hydraulic fracturing fluids. Similarly to exposures to the substance as delivered to operational sites, levels of exposure to the substance in these fluids will vary depending on work practices. However, given the low concentration in hydraulic fracturing fluids, exposure to the substance via these fluids is of low concern or workers.

65.4.2.2 Long-term health risks

From the hazard characterisation, the critical (most sensitive) adverse health effect for repeated exposures to the substance is decreased bodyweight. The NOAEL established for this effect is 600 mg/kg bw/day.

MOEs for adverse health effects from repeated occupational exposures are calculated by comparing the NOAEL for this effect with exposures estimated for different occupational activities and combined activities (Table D.317).

Table D.317 Margins of Exposure calculated for hydraulic fracturing occupational activities

Activity*	Margin of Exposure (MOE)
Mixing/blending of hydraulic fracturing chemicals	n.d.
Cleaning and maintenance (hydraulic fracturing)	n.d.
Combined exposure Mixing/blending and cleaning and maintenance (hydraulic fracturing)	n.d.

n.d. – not disclosed. * MOEs for transport/storage, injection and produced water handling are not calculated due to negligible human exposures (Table D.314).

Based on uncertainty factors derived for this risk characterisation, the MOEs indicate that the substance is of low concern for workers from repeated exposures during certain operations.

65.4.3 Public health risks

65.4.3.1 Acute health risks

Given industrial use of the substance for coal seam gas extraction, the public is unlikely to come into contact with the substance as delivered to operational sites. Therefore, the substance in this form is of low concern for the public.

65.4.3.2 Long-term health risks

The public is most likely to come into contact with the substance via environmental contamination of water used for drinking, bathing and recreational uses.

Based on the critical health effect and NOAEL established for this effect, MOEs were calculated for adults and children for various exposure scenarios (Table D.318).

Table D.318 Margins of Exposure calculated for different public exposure scenarios

Public exposure scenario*	Margin of Exposure (MOE) (ADULT)	Margin of Exposure (MOE) (CHILDREN)
Accidental bulk spill during transport and surface runoff		
Combined exposure from bulk spill – surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.
Long-term subsurface leak from flowback and / or produced water storage pond		
Combined exposure from subsurface leak – groundwater/surface water use Drinking and bathing in contaminated groundwater plus swimming in contaminated surface water	n.d.	n.d.
Combined exposure from subsurface leak - surface water use Drinking, bathing and swimming in contaminated surface water	n.d.	n.d.

n.d. – not disclosed. * MOEs for a bulk spill from flowback and / or produced water storage pond are not calculated due to negligible PECs and internal human doses (Table D.315 and

Table D.316).

Based on uncertainty factors derived for this risk characterisation and conservative assumptions within the exposure modelling, the MOEs are suggestive of a potential concern for children from repeated exposures based on the scenario of a bulk transport spill.

It should be noted that as much as some MOEs suggest a potential concern for the public for particular exposure scenarios, these MOEs are based on PECs derived from conservative (Tier 1) exposure modelling and so are likely to be overestimates of actual health risks. A sensitivity analysis of the exposure modelling across all drilling and hydraulic fracturing chemicals using less conservative modelling assumptions for certain public exposure scenarios revealed risk estimates suggestive of a health concern for only small numbers of

chemicals (NICNAS 2017b). Establishing the true level of public health risk for any particular chemical would require more information to enable refined exposure estimates or environmental monitoring data.

65.4.4 Conclusions

65.4.4.1 Occupational health risks

The substance as delivered to operational sites is of potential concern for workers during operations based on the potential for skin irritation and skin sensitisation.

Exposure to the substance via hydraulic fracturing fluids is of low concern for workers.

Calculated MOEs indicate that the substance is of low concern for workers from repeated exposures during operations.

65.4.4.2 Public health risks

The public is unlikely to come into contact with the substance as delivered to operational sites and so the substance in this form is of low concern for the public.

For repeated exposures of the public via environmental contamination, calculated MOEs based on conservative (Tier 1) exposure modelling are suggestive of a potential concern for children for the scenario of exposures from a bulk transport spill.

However, these public health risks were estimated using conservative exposure modelling and so are likely to be overestimates of actual health risks. Estimating the true level of risk would require more information to enable refined exposure estimates or environmental monitoring data.

65.5 Risk mitigation measures

The following risk mitigation measures arise from the risk assessment. Implicit in these measures is that best practice chemical management is implemented to minimise worker and public exposure.

65.5.1 Obligations under workplace health and safety legislation

As noted in the hazard assessment report (NICNAS 2017c), the chemical requires classification as a workplace hazardous chemical. Accordingly, the classification of the chemical has been forwarded by NICNAS to Safe Work Australia for inclusion in the Hazardous Substances Information System.

Risk estimates for this chemical suggest a potential concern for workers.

For such chemicals, persons conducting a business or undertaking (such as an employer) have obligations under workplace health and safety legislation as adopted by the relevant state or territory to manage risks associated with the use and handling of chemicals. Obligations involve site-specific risk assessments and the implementation of control measures to manage risks.

Measures to eliminate or minimise risk arising from storing, handling and using the chemical depend on the physical form and the manner in which the chemical is used.

Further information on control measures is available in the human health risk assessment summary report (NICNAS 2017a).

65.5.2 Control measures available to minimise risks to the public

65.5.2.1 Transport

For this chemical, risk estimates from conservative exposure modelling suggest a potential concern from contamination of surface water from a transport spill.

The Australian Code for the Transport of Dangerous Goods by Road or Rail (ADG Code) provides detailed technical requirements for the transportation of dangerous goods. Risk mitigation measures from the ADG Code to address the potential environmental and public health impacts for such chemicals include reviews of transport routes and procedures, worker training and incident contingency plans.

Further information on these measures is available in the human health risk assessment summary report (NICNAS 2017a).

65.6 References

- NICNAS (YEAR) Chemical Assessment Report. National Industrial Chemicals Notification and Assessment Scheme.
- NICNAS (2017a) Human health risks associated with surface handling of chemicals used in coal seam gas extraction, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.
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