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

Technical report number 12

Human health hazards of chemicals associated with coal seam gas extraction in Australia

This report was prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Australian Government
Department of the Environment and Energy
Department of Health
National Industrial Chemicals Notification and Assessment Scheme

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Reports in this series

The full set of technical reports in this series and the partner agency responsible for each is listed below.

Technical report number	Title	Authoring agency
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3	Literature review: Environmental risks posed by chemicals used coal seam gas operations	Department of the Environment and Energy
4	Literature review: Hydraulic fracture growth and well integrity	CSIRO
5	Literature review: Geogenic contaminants associated with coal seam gas operations	CSIRO
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Foreword

Purpose of the Assessment

This report is one in a series of technical reports that make up the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (the Assessment).

Many chemicals used in the extraction of coal seam gas are also used in other industries. The Assessment was commissioned by the Australian Government in June 2012 in recognition of increased scientific and community interest in understanding the risks of chemical use in this industry. The Assessment aimed to develop an improved understanding of the occupational, public health and environmental risks associated with chemicals used in drilling and hydraulic fracturing for coal seam gas in an Australian context.

This research assessed and characterised the risks to human health and the environment from surface handling of chemicals used in coal seam gas extraction during the period 2010 to 2012. This included the transport, storage and mixing of chemicals, and the storage and handling of water pumped out of coal seam gas wells (flowback or produced water) that can contain chemicals. International evidence[1] showed the risks of chemical use were likely to be greatest during surface handling because the chemicals were undiluted and in the largest volumes. The Assessment did not consider the effects of chemical mixtures that are used in coal seam gas extraction, geogenic chemicals, or potential risks to deeper groundwater.

The Assessment findings significantly strengthen the evidence base and increase the level of knowledge about chemicals used in coal seam gas extraction in Australia. This information directly informs our understanding of which chemicals can continue to be used safely, and which chemicals are likely to require extra monitoring, industry management and regulatory consideration.

Australia's regulatory framework

Australia has a strong framework of regulations and industrial practices which protects people and the environment from adverse effects of industrial chemical use. For coal seam gas extraction, there is existing legislation, regulations, standards and industry codes of practice that cover chemical use, including workplace and public health and safety, environmental protection, and the transport, handling, storage and disposal of chemicals. Coal seam gas projects must be assessed and approved under relevant Commonwealth, state and territory environmental laws, and are subject to conditions including how the companies manage chemical risk.

Approach

Technical experts from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Commonwealth Scientific and Industrial Research Organisation (CSIRO), and the Department of the Environment and Energy conducted the Assessment. The Assessment drew on technical expertise in chemistry, hydrogeology, hydrology, geology, toxicology, ecotoxicology, natural resource management and risk assessment. The Independent Expert Scientific Committee on Coal Seam Gas and Large Coal Mining

[1] See Mallants et al. 2017; Jeffrey et al. 2017; Adgate et al. 2014; Flewelling and Sharma 2014; DEHP 2014; Stringfellow et al. 2014; Groat and Grimshaw 2012; Vidic et al. 2013; Myers 2012; Rozell and Reaven 2012; The Royal Society and The Royal Academy of Engineering 2012; Rutovitz et al. 2011.

Development (IESC) provided advice on the Assessment. Experts from the United States Environmental Protection Authority, Health Canada and Australia reviewed the Assessment and found the Assessment and its methods to be robust and fit-for-purpose.

The Assessment was a very large and complex scientific undertaking. No comparable studies had been done in Australia or overseas and new models and methodologies were developed and tested in order to complete the Assessment. The Assessment was conducted in a number of iterative steps and inter-related processes, many of which needed to be done in sequence (Figure F.1). There were two separate streams of analysis - one for human health and one for the environment. The steps included for each were: literature reviews; identifying chemicals used in drilling and hydraulic fracturing for coal seam gas extraction; developing conceptual models of exposure pathways; models to predict soil, surface and shallow groundwater concentrations of identified chemicals; reviewing information on human health hazards; and identifying existing Australian work practices, to assess risks to human health and the environment.

The risk assessments did not take into account the full range of safety and handling precautions that are designed to protect people and the environment from the use of chemicals in coal seam gas extraction. This approach is standard practice for this type of assessment. In practice, safety and handling precautions are required, which means the likelihood of a risk occurring would actually be reduced for those chemicals that were identified as a potential risk to humans or the environment.

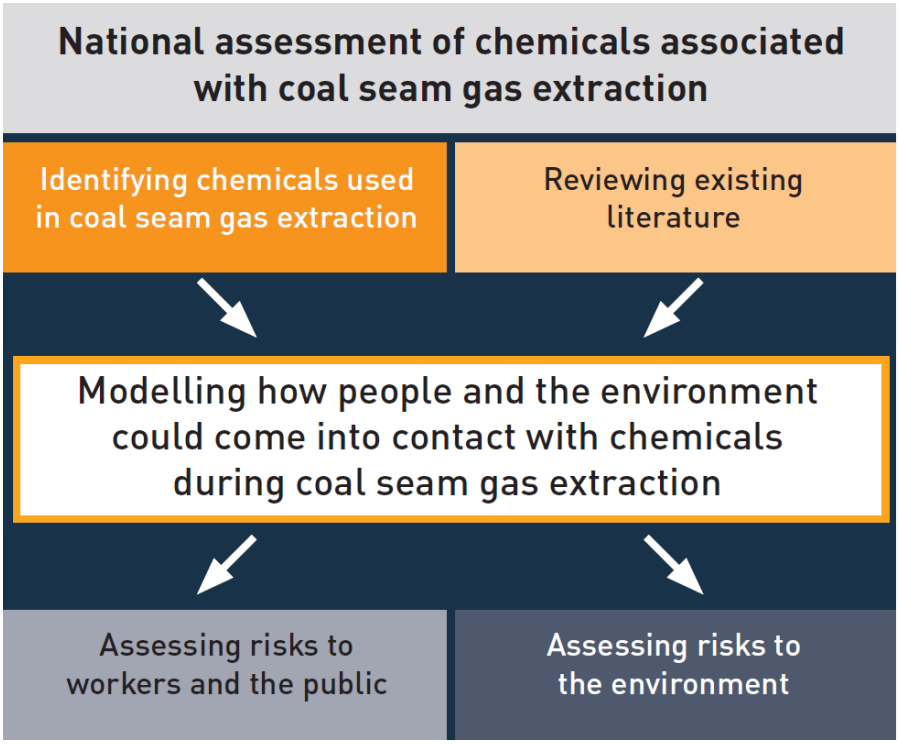

Figure F.1 Steps in the assessment

Collaborators

The Australian Government Department of the Environment and Energy designs and implements policies and programs, and administers national laws, to protect and conserve the environment and heritage, promote action on climate change, advance Australia's interests in the Antarctic, and improve our water use efficiency and the health of Australia's river systems.

Within the Department, the Office of Water Science is leading the Australian Government's efforts to improve understanding of the water-related impacts of coal seam gas and large coal mining. This includes managing the Australian Government's program of bioregional assessments and other priority research, and providing support to the Independent Expert Scientific Committee on Coal Seam Gas and Large Coal Mining Development (IESC). The IESC provides independent, expert scientific advice on coal seam gas and large coal mining proposals as requested by the Australian Government and state government regulators, and advice to the Australian Government on bioregional assessments and research priorities and projects.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is a statutory scheme administered by the Australian Government Department of Health. NICNAS aids in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use.

CSIRO, the Commonwealth Scientific and Industrial Research Organisation, is Australia's national science agency and one of the largest and most diverse research agencies in the world. The agency's research is focused on building prosperity, growth, health and sustainability for Australia and the world. CSIRO delivers solutions for agribusiness, energy and transport, environment and natural resources, health, information technology, telecommunications, manufacturing and mineral resources.

This report: *Human health hazards of chemicals associated with coal seam gas extraction in Australia*

This report, together with the reports *Chemicals of low concern for human health based on an initial assessment of hazards* (NICNAS 2017a) and *Human health risks associated with surface handling of chemicals used in coal seam gas extraction* (NICNAS 2017b), describes the 'assessing risks to workers and the public' stage of the *Assessment*.

An investigation undertaken in the initial stages of the Assessment identified 113 chemicals used in drilling and hydraulic fracturing for coal seam gas extraction in Australia during the period 2010 to 2012 (NICNAS 2017c).

The 'assessing risk to workers and the public' stage of the assessment began with an initial screening to identify which of these 113 chemicals were of low human health hazard and therefore of low concern for human health. This initial screening identified 44 chemicals as being of low concern for human health (NICNAS 2017a). These chemicals were excluded from further human health assessment given their low concern for human health. A total of 69 chemicals therefore required human health hazard assessments and are the subject of this report.

This report provides:

- a description of the hazard assessment methodology used for the chemicals associated with coal seam gas extraction in Australia
- results of the human health hazard assessments
- human health hazard assessment sheets for the 69 chemicals associated with coal seam gas extraction in Australia that were not identified as being of low concern as a result of the initial screening process.

Based on the hazard assessments, 57 of the 69 chemicals are considered hazardous, according to Safe Work Australia's Approved Criteria for Classifying Hazardous Substances. At the time of assessment, 30 of the 57 hazardous chemicals were not listed in the

Hazardous Substances Information System (HSIS) and NICNAS recommended to Safe Work Australia appropriate hazard classifications for listing these chemicals on HSIS. In addition, three of the 27 classified chemicals required new hazard classifications in addition to their existing hazard classifications. The model Work Health and Safety (WHS) Regulations mandate that the hazards of a chemical as determined by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) must be included accurately by the manufacturer or importer of a hazardous chemical in safety data sheets (SDS) and on labels. Listing in the HSIS provides information on the hazards of the chemical. Additionally, the WHS Regulations oblige industry to identify, assess and manage risks to health and safety associated with using, handling and storing a hazardous chemical in the workplace and that measures to control risks are reviewed and revised as required (Safe Work Australia 2016).

Human health risk is a product of the hazard of a chemical and the level of exposure of a person to the chemical. This means that chemicals found to be a hazard to human health do not necessarily present a risk to workers or the public when used in coal seam gas extraction. Accordingly, the last step in the 'assessing risk to workers and the public' stage of the Assessment was to combine information about hazard from this report with modelled information about potential exposure to characterise the human health risks arising from the use of the 69 chemicals in coal seam gas extraction in Australia. The results are described in *Human health risks associated with surface handling of chemicals used in coal seam gas extraction* (NICNAS 2017b).

Abbreviations

General abbreviations	Description
ADWG	Australian Drinking Water Guidelines
ATSDR	Agency for Toxic Substances and Disease Registry
CAS	Chemical Abstract Service
CBI	Confidential business information
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DSL	Domestic Substances List
EPA	Environmental Protection Agency
EU	European Union
FSANZ	Food Standards Australia New Zealand
GA	Geoscience Australia
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
IARC	International Agency for Research on Cancer
IESC	Independent Expert Scientific Committee
IMAP	Inventory Multi-tiered Assessment and Prioritisation
IPCS	International Programme on Chemical Safety
IRIS	Integrated Risk Information System
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No Observed Adverse Effect Level
PEC	Priority Existing Chemical
QSAR	Quantitative Structure-Activity Relationship
RED	Reregistration Eligibility Decision
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons

General abbreviations	Description
US	United States
UVCB	Unknown or Variable composition, Complex reaction products or Biological materials
WHO	World Health Organisation

Glossary

Term	Description
adverse effect	Change in the morphology, physiology, growth, development, reproduction, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences
coal seam	Coal seams or coal deposits are layers containing coal (sedimentary rock). Coal seams store both water and gas. Coal seams generally contain more salty groundwater than aquifers that are used for drinking water or agriculture
coal seam gas	A form of natural gas (generally 95 to 97% pure methane, CH_4) typically extracted from permeable coal seams at depths of 300 to 1 000 m. Also called coal seam methane (CSM) or coalbed methane (CBM)
exposure assessment	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives)
flowback water	The initial flow of water returned to a well after fracture stimulation and prior to production. This is the fluid that flows back, or is pumped back, to surface following hydraulic fracturing but prior to gas production. Some of this water is returned fracturing fluid and some is natural 'formation water' (often salty water that is naturally present in the coal seam)
hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or sub(population) is exposed to that agent
hazard assessment	A process designed to determine the possible adverse effects when an organism, system, or sub(population) could be exposed. The process includes hazard identification and hazard characterisation. The process focuses on hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step
hazard characterisation	The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects
hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population
hydraulic fracturing	Also known as 'fracking', 'fraccing' or 'fracture stimulation', is one process by which hydrocarbon (oil and gas) bearing geological formations are 'stimulated' to enhance the flow of hydrocarbons and other fluids towards the well. In most cases is only undertaken where the permeability of the formation is initially insufficient to support sustained flow of gas. The hydraulic fracturing process involves the injection of fluids, gas, proppant and other additives under high pressure into a geological formation to create a conductive fracture. The fracture extends from the well into the coal reservoir, creating a large surface area through which gas and water are produced and then transported to the well via the conductive propped fracture channel
hydraulic fracturing	A fluid injected into a well under pressure to create or expand fractures in

Term	Description
fluid	a target geological formation (to enhance production of natural gas and / or oil). It consists of a primary carrier fluid (usually water or gel based), a proppant and one or more additional chemicals to modify the fluid properties
low concern	A chemical of low human health hazard and therefore inherently low concern for human health. Chemicals of low concern are considered to have a low likelihood of causing adverse human health effects should an exposure occur
produced water	Water that is pumped out of coal seams in order to release the natural gas during the production phase. Some of this water is returned fracturing fluid and some is natural 'formation water' (often salty water that is naturally present in the coal seam). This produced water moves through the coal formation to the well along with the gas and is pumped out via the wellhead
proppant	A component of the hydraulic fracturing fluid system comprised of sand, ceramics or other granular material that 'prop' open fractures to prevent them from closing when the injection is stopped
Quantitative Structure-Activity Relationship (QSAR)	An approach designed to find relationships between chemical structure (or structural-related properties) and biological activity (or target property) of studied compounds. Quantitative relationships are derived for continuous data (e.g. toxic potency data) while qualitative relationships are derived from non-continuous data (e.g. “yes” or “no” data)
risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent
risk assessment (chemicals)	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target organism
toxicity	Inherent property of an agent to cause an adverse biological effect
validation rules	Criteria used to determine if a chemical is of low concern for human health, or not

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1 Hazard assessment methodology

The International Programme on Chemical Safety (IPCS) of the World Health Organisation (WHO) defines hazard as the inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent (IPCS 2004). For a chemical, hazard identification establishes its toxicity and identifies the set of inherent properties that makes it capable of causing adverse effects. Assessment of the risk posed by the use of a chemical considers the chemical's hazard in the context of the degree to which an organism is likely to be exposed to the chemical.

1.1 Identification of chemicals used in coal seam gas extraction in Australia

The identification of the drilling and hydraulic fracturing chemicals used in coal seam gas extraction in Australia in the period 2010 to 2012 is based on the most up to date and relevant Australian information available at the time. This information is based on:

- an industry survey of companies involved in the Australian coal seam gas industry, conducted in late 2012
- a review of publicly available lists of chemicals reportedly used in coal seam gas extraction in Australia, conducted in 2013
- supplementary data sought from companies to fill data gaps on certain chemicals, provided in 2015.

A total of 113 chemicals were identified as being used in Australia in the period 2010 to 2012 through the voluntary survey and from publicly available lists.

More details of processes used for the compilation of this list can be found in the National Chemicals Assessment report, *Identification of chemicals associated with coal seam gas extraction in Australia* (NICNAS 2017c).

1.2 Screening of chemicals of low concern for human health

The 113 chemicals used in coal seam gas extraction in Australia were screened to identify chemicals of low hazard and therefore of inherently low concern for human health. The screening approach used in this assessment to identify chemicals of low concern uses general criteria and applies to workers and the public, so the chemicals identified using this screening process are considered to be of low concern to both the public and workers.

The approach used to identify chemicals of low concern for human health is based on the NICNAS Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework (NICNAS 2013a and 2013b). Details of the approach, the validation rules, and results can be found in the report entitled *Chemicals of low concern for human health based on an initial assessment of hazards* (NICNAS 2017a). Of the original 113 chemicals, a total of 44 (discrete chemicals and polymers) were initially identified as chemicals of low concern for human health. The remaining 69 chemicals required further assessment (described in this report).

The initial group of 44 chemicals of low concern for health, listed by their Chemical Abstract Service registration numbers (CAS RNs) and common names, are presented in Table 1.1. Although some chemicals were subject to commercial-in-confidence claims, their details

were provided to NICNAS. In the table, the CAS RNs of those chemicals subject to commercial-in-confidence claims have been designated as confidential business information (CBI) and the generic chemical names as provided by the companies have been included.

Table 1.1 Coal seam gas chemicals found to be of low concern for human health following initial screening (from NICNAS 2017a)

	CAS RN	Chemical name	Common name
1	10377-60-3	Nitric acid, magnesium salt (2:1)	Magnesium nitrate
2	11138-66-2	Xanthan gum	
3	124-38-9	Carbon dioxide	
4	127-09-3	Acetic acid, sodium salt (1:1)	Sodium acetate
5	1302-78-9	Bentonite	Bentonite clay
6	1317-65-3	Limestone	Limestone
7	144-55-8	Carbonic acid sodium salt (1:1)	Sodium bicarbonate, baking soda
8	14807-96-6	Talc ($Mg_3H_2(SiO_3)_4$)	Talc
9	25038-72-6	2-Propenoic acid, methyl ester, polymer with 1,1-dichloroethene	Vinylidene chloride, methyl acrylate polymer
10	463-79-6	Carbonic acid	Carbonated water
11	533-96-0	Carbonic acid, sodium salt (2:3)	Sodium sesquicarbonate
12	56-81-5	1,2,3-Propanetriol	Glycerol
13	6381-77-7	D-erythro-Hex-2-enonic acid, γ-lactone, sodium salt (1:1)	Sodium erythorbate
14	67-48-1	Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1)	Choline chloride
15	68130-15-4	Guar gum, carboxymethyl 2-hydroxypropyl ether, sodium salt	Sodium carboxymethyl hydroxypropyl guar
16	7447-40-7	Potassium chloride (KCl)	Sylvite
17	7647-14-5	Sodium chloride (NaCl)	Common salt
18	7727-37-9	Nitrogen	Nitrogen
19	7727-43-7	Sulfuric acid, barium salt (1:1)	Barium sulfate
20	7732-18-5	Water	Water
21	7757-82-6	Sulfuric acid sodium salt (1:2)	Sodium sulfate
22	7758-16-9	Diphosphoric acid, sodium salt (1:2)	Sodium pyrophosphate
23	7778-80-5	Sulfuric acid potassium salt (1:2)	Potassium sulfate
24	7783-20-2	Sulfuric acid ammonium salt (1:2)	Ammonium sulfate
25	7786-30-3	Magnesium chloride ($MgCl_2$)	
26	77-92-9	1,2,3-Propanetricarboxylic acid,	Citric acid

	CAS RN	Chemical name	Common name
		2-hydroxy-	
27	9000-30-0	Guar gum	Guar gum
28	9000-70-8	Gelatins	Gelatins
29	9003-05-8	2-Propenamide, homopolymer	
30	9003-06-9	2-Propenoic acid, polymer with 2-propenamide	Polyacrylamide
31	9004-62-0	Cellulose, 2-hydroxyethyl ether	Hydroxyethyl cellulose
32	n.s.	Natural fibres I	
33	n.s.	Natural fibres II	
34	CBI	Natural fibres III	
35	n.s.	Nut hulls	
36	CBI	Polyacrylamide/polyacrylate copolymer	
37	n.s.	Polyanionic cellulose PAC	
38	n.s.	Polyesters	
39	CBI	Polymer I	
40	CBI	Polymer II	
41	CBI	Polysaccharide	
42	n.s.	Walnut hulls	
43	n.s.	Wood dust	
44	n.s.	Wood fibre	

n.s. = not specified

The 69 chemicals that were identified as requiring further assessment of the hazards are presented in Table 1.2 (listed by their CAS RNs, chemical names, and common names). Details of chemicals subject to commercial-in-confidence claims were provided to NICNAS. In the table, the CASRNs of those chemicals subject to commercial-in-confidence claims have been designated as 'CBI' and the generic chemical names as provided by the companies have been included. Consistent with the requirements of the ICNA Act, CAS RNs for natural substances were not provided.

Table 1.2 Chemicals requiring further human health hazard assessment following screening

	CAS RN	Chemical name	Common name
1	10043-35-3	Boric acid (H_3BO_3)	Boric acid
2	10043-52-4	Calcium chloride ($CaCl_2$)	Calcium chloride
3	102-71-6	Ethanol, 2,2',2''-nitrilotris -	Triethanolamine
4	107-21-1	1,2-Ethanediol	Ethylene glycol
5	107-22-2	Ethanedial	Ethanedial

	CAS RN	Chemical name	Common name
6	108-10-1	2-Pentanone, 4-methyl-	Methyl isobutyl ketone
7	111-30-8	Pentanedial	Glutaraldehyde
8	111-76-2	Ethanol, 2-butoxy-	Butoxyethanol
9	111-90-0	Ethanol, 2-(2-ethoxyethoxy)-	Diethylene glycol ethyl ether
10	112926-00-8	Silica gel, pptd., cryst.-free	Precipitated silica
11	12008-41-2	Boron sodium oxide	Sodium borate
12	1303-96-4	Borax ($B_4Na_2O_7.10H_2O$)	Sodium tetraborate
13	1305-62-0	Calcium hydroxide ($Ca(OH)_2$)	Slaked lime
14	1305-78-8	Calcium oxide	Lime
15	1310-73-2	Sodium hydroxide (Na(OH))	Caustic soda
16	141-43-5	Ethanol, 2-amino-	Ethanolamine
17	144588-68-1	Bauxite ($Al_2O_3.xH_2O$), sintered	Sintered bauxite
18	14464-46-1	Cristobalite (SiO_2)	Cristobalite
19	14808-60-7	Quartz (SiO_2)	Quartz
20	15468-32-3	Tridymite (SiO_2) (9CI)	Tridymite
21	26038-87-9	Boric acid (H_3BO_3), compound. with 2-aminoethanol (1:?)	MEA polyborate
22	26062-79-3	2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), homopolymer	Polydimethyldiallylammonium chloride
23	26172-55-4	3(2H)-Isothiazolone, 5-chloro-2-methyl-	Methylchloroisothiazolinone
24	2634-33-5	1,2-Benzisothiazol-3(2H)-one	Benzisothiazolinone
25	2682-20-4	3(2H)-Isothiazolone, 2-methyl-	Methylisothiazolone
26	497-19-8	Carbonic acid sodium salt (1:2)	Soda ash
27	52-51-7	1,3-Propanediol, 2-bromo-2-nitro-	Bronopol
28	55566-30-8	Phosphonium, tetrakis(hydroxymethyl)-, sulfate (2:1)	THPS
29	584-08-7	Carbonic acid, potassium salt (1:2)	Potassium carbonate
30	64-02-8	Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:4)	Tetrasodium EDTA
31	6410-41-9	2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[2-[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]diazenyl]-3-hydroxy-	Pigment Red 5
32	64-17-5	Ethanol	Ethanol
33	64-19-7	Acetic acid	Acetic acid
34	64742-47-8	Distillates (petroleum), hydrotreated light	Deodorised kerosene

	CAS RN	Chemical name	Common name
35	67-56-1	Methanol	Methanol
36	67-63-0	2-Propanol	Isopropanol
37	68187-17-7	Sulfuric acid, mono-C_6-C_{10}-alkyl esters, ammonium salts	C_6-C_{10} linear alkyl sulfate, ammonium salt
38	68439-45-2	Alcohols, C_6-C_{12}, ethoxylated	C_6-C_{12} ethoxylated alcohols
39	68647-72-3	Terpenes and Terpenoids, sweet orange-oil	Sweet orange oil terpenes
40	75-57-0	Methanaminium, N,N,N-trimethyl-, chloride (1:1)	Tetramethylammonium chloride
41	7631-86-9	Silica	Amorphous silica
42	7647-01-0	Hydrochloric acid	Hydrochloric acid
43	7681-52-9	Hypochlorous acid, sodium salt (1:1)	Sodium hypochlorite
44	7722-84-1	Hydrogen peroxide (H_2O_2)	Hydrogen peroxide
45	7727-54-0	Peroxydisulfuric acid ($[(HO)S(O)_2]2O_2$), ammonium salt (1:2)	Ammonium persulfate
46	7757-83-7	Sulfurous acid, sodium salt (1:2)	Sodium sulphite
47	7758-19-2	Chlorous acid, sodium salt (1:1)	Sodium chlorite
48	7772-98-7	Thiosulfuric acid ($H_2S_2O_3$), sodium salt (1:2)	Sodium thiosulfate
49	7775-27-1	Peroxydisulfuric acid ($[(HO)S(O)_2]2O_2$), sodium salt (1:2)	Sodium persulfate
50	81741-28-8	Phosphonium, tributyltetradecyl-, chloride (1:1)	Tributyltetradecyl phosphonium chloride
51	9012-54-8	Cellulase	Cellulase
52	9025-56-3	Hemicellulase	Hemicellulase
53	91053-39-3	Diatomite, calcined	Calcined silica
54	90622-53-0	Alkanes, C_{12}-$_{26}$ branched and linear	Alkanes, $C_{12\text{-}26}$ branched and linear
55	CBI	2-Ethylhexanol heavies	
56	CBI	Amine salt	
57	CBI	Enzyme	
58	CBI	Ester alcohol	
59	CBI	Ethoxylated fatty acid I	
60	CBI	Ethoxylated fatty acid II	
61	CBI	Ethoxylated fatty acid III	
62	CBI	Fatty acids ester	
63	CBI	Inner salt of alkyl amines	
64	CBI	Organic acid salt	

	CAS RN	Chemical name	Common name
65	CBI	Organic sulfate	
66	CBI	Polyamine	
67	CBI	Polymer with substituted alkylacrylamide salt	
68	CBI	Quaternary amine	
69	CBI	Terpenes and terpenoids	

Exclusion of the 69 chemicals from the current list of chemicals of low concern for human health does not imply that these chemicals represent an actual risk to human health, as some of these chemicals may have not been previously evaluated by the agencies that developed the existing national or international lists of substances considered to be of low concern. Further analysis of the hazards may result in a conclusion that a number of these chemicals are of low concern to human health.

1.3 Data sources used in the assessment

Publicly available Australian and international sources were searched for information on the human health hazards of the chemicals. NICNAS used commercial databases and databases containing peer-reviewed information. In addition, international reviews on chemicals from reputable organisations published in the last 10 years, where available, were consulted. Where reviews were not available, journal articles, industry reports, and other publications were evaluated. The databases accessed were:

- Galleria Chemica
- Registry of Toxic Effects of Chemical Substances (RTECS)
- ChemID*plus*
- Hazardous Substances Data Bank (HSDB)
- Organisation for Economic Co-operation and Development (OECD)
- eChemPortal
- SciFinder.

The national and international reviews that were used were:

- NICNAS Priority Existing Chemical (PEC) and new chemical assessment reports
- reports from the Canadian categorisation of the Domestic Substances List (DSL) and the Challenge Program
- reports from European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and EU Classification and Labelling Program
- Scientific opinions on cosmetic substances by European Commission committees
- reports available through several Programs in the United States (US) such as US Environmental Protection Agency‘s (US EPA) High Production Volumes Program, US EPA Action Plans, Agency for Toxic Substances and Disease Registry (ATSDR) reports, US EPA Integrated Risk Information System (IRIS) and the US EPA Reregistration Eligibility Decision (RED)

- OECD High Production Volume Programme and Cooperative Chemical Assessment Programme Reports
- International Programme on Chemical Safety (IPCS) Publications
- International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans.

Current Australian and international regulatory controls in place for each of the chemicals were identified. The Australian regulatory controls examined were:

- Australian Drinking Water Guidelines (ADWG)
- Australian Food Standards
- The Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons [SUSMP])
- Hazardous Substances Information System (HSIS).

These regulatory controls were examined as the ADWG, the SUSMP, and Food Standards provide protection for the public. The ADWG, the SUSMP, and Food Standards list chemicals based on their risks. The classifications of chemicals on the HSIS provide worker protection and the criteria used for the listing are hazard rather than risk based.

The information obtained through the comprehensive literature search process was summarised for each chemical. The health hazards were characterised by analysing the following:

- toxicokinetics (absorption, distribution, metabolism, and excretion)
- acute oral, dermal and inhalation toxicity
- irritation / corrosivity
- sensitisation
- repeat oral, dermal and inhalation dose toxicity
- genotoxicity
- carcinogenicity
- reproductive toxicity
- other health effects.

Ten chemicals had limited or no toxicity data. The 10 chemicals consisted of six polymers and four substances of unknown or variable composition, complex reaction products or biological materials (UVCB). The companies that notified these chemicals were contacted for toxicity data. In the absence of these data, alternative approaches were applied. Four approaches (i.e. identifying suitable analogues, screening of functional groups, using additional Quantitative Structure-Activity Relationship (QSAR) (OECD 2013) models such as OASIS-TIMES, and searching for data on analogous chemicals and chemical classes) were considered in determining the likely hazards of these chemicals. Consistent with the guiding principles of the OECD Guidance on Grouping of Chemicals (OECD 2007), the suitability of the analogues was justified based on common features of the chemicals such as chemical structure, functional groups, physicochemical properties, mammalian toxicity, and / or mode / mechanism of action. The methods consisted of the following:

- for two polymers, screening was based on functional groups and QSAR data on the constituent monomers

- for two polymers, data were obtained from chemicals belonging to similar chemical classes and QSAR modeling based on specific chain lengths
- for two polymers, data were obtained from the components of the polymer as well as from polymers from the same chemical class
- for three UVCBs containing a large number of chemical components belonging to a related chemical category, data were obtained from analogue chemicals in the category
- for one UVCB containing only two components, data were obtained from a review of homologues in a related chemical class and QSAR modelling of one of the components.

Following the analysis, conclusions were formulated for each of the human health endpoints for each chemical. Where available, quantitative toxicity values were identified for the various health endpoints, to allow quantitative risk assessments to be subsequently made using potential exposure pathways. The absorption or uptake rates were determined from analysis of the toxicokinetics data. The critical health effects were then identified. For acute effects, such as acute toxicity, the median lethal dose (LD50) or concentration (LC50) was identified. For the chronic effects, the most appropriate Lowest Observed Adverse Effect Level (LOAEL) or No Observed Adverse Effect Level (NOAEL) was determined for use in the risk assessment.

The results for each human health endpoint were compared with the classification criteria set out in the Approved Criteria for Classifying Hazardous Substances (NOHSC 2004) and the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (UNECE 2009). Where a chemical was classified as hazardous for a particular endpoint in the HSIS, the results of this hazard assessment was compared with the existing classification.

Where a chemical was not classified as hazardous, but was indicated to be so by the results from this current assessment, NICNAS recommended that Safe Work Australia include the appropriate classification for particular endpoint(s) based on the information reviewed.

The hazard classification is important in the safe management of hazardous chemicals in the workplace. Recommendations to Safe Work Australia are made on the human health hazards resulting from the human health hazard assessments.

The determination for listing of chemicals in the ADWG, Food Standards and SUSMP are based on risk evaluations. Recommendations for inclusion of chemicals not currently listed in the ADWG, Food Standards and SUSMP therefore cannot be made based on hazard assessments alone.

2 Hazard assessment findings

This section provides the assessment findings from the hazard evaluations of the 69 chemicals requiring further assessment.

In addition to the results of the hazard evaluations of the 69 chemicals, details of some current regulatory controls for these chemicals, as well as controls recommended by NICNAS, such as hazard classifications, are also described in this section. The individual human health hazard assessments of the 69 chemicals are provided in Appendix A.

The hazard assessment findings for each chemical, or groups of chemicals, outlined in this section describe regulatory controls (in Australia and overseas), and a health hazard characterisation based on information available at the time of assessment. Subsequent to completion of these hazard assessments, NICNAS forwarded recommendations to Safe Work Australia about the classification of chemicals in the HSIS. Consequently, the current regulatory status of individual chemicals may now reflect adoption of these recommendations by Safe Work Australia.

The criteria for determining if a chemical is hazardous were developed for the occupational sector (NOHSC 2004). They are however applicable to public health as well. Fifty-seven of the 69 chemicals were found to be hazardous because of effects produced at the local point of contact (such as skin or eye irritation) or adverse effects at a location distant from the initial point of contact (systemic effects).

The systemic effects for the chemicals varied from effects on single exposures (acute effects), or adverse health effects on repeated exposures (chronic effects). Some chemicals produced a combination of adverse effects (both acute and chronic effects along with local effects). Based on the hazard assessment, regulatory controls in the form of hazard classifications have been recommended by NICNAS for the 57 chemicals. The current regulatory controls and regulatory controls recommended by NICNAS for these 57 chemicals are described further in Sections 2.1 and 2.2, respectively.

NICNAS did not recommend that the remaining 12 of the 69 assessed chemicals be classified as hazardous and listed in the HSIS (Table 2.1). For four of the 12 chemicals (tridymite, polydimethyldialylammonium chloride, calcined silica and polyamine) the toxicity information available for hazard assessment was insufficient to consider classification (as described in Appendix A). For eight chemicals the toxicity information available was sufficient but did not warrant classification.

Table 2.1 Chemicals not currently listed in HSIS and that NICNAS has not recommended for hazard classification

ID	CAS RN	Common name
1	111-90-0	Diethylene glycol ethyl ether
2	112926-00-8	Precipitated silica*
3	15468-32-3	Tridymite*
4	26062-79-3	Polydimethyldiallylammonium chloride
5	6410-41-9	Pigment Red 5
6	7631-86-9	Amorphous silica*

ID	CAS RN	Common name
7	7772-98-7	Sodium thiosulfate
8	91053-39-3	Calcined silica
9	CBI	Ester alcohol
10	CBI	Ethoxylated fatty acid II
11	CBI	Fatty acids ester
12	CBI	Polyamine

** These chemicals have existing exposure standards in the HSIS for inhalable 'nuisance' dusts but are not otherwise classified or recommended by NICNAS for classification for hazards.*

2.1 Current regulatory and other controls

As indicated earlier, some specific Australian regulatory controls in place for the chemicals were reviewed. The sections below provide an analysis of the regulatory controls for the 69 chemicals.

2.1.1 Chemicals currently listed in the ADWG

The National Health and Medical Research Council's (NHMRC) ADWG includes health and aesthetic guideline values for contaminants that may be present in drinking water supplies (NHMRC 2011). ADWG values are set based on best available scientific evidence in defining safe and good quality water and provide a framework for the management of drinking water supplies. ADWG values currently exist for 20 of the 69 chemicals.

2.1.2 Chemicals currently listed in the Australian Food Standards

The Australian Food Standards administered by Food Standards Australia New Zealand (FSANZ) include requirements for chemicals approved as additives in food and other food-related preparations (FSANZ 2013). Twenty-four of the 69 chemicals have existing food standards for various purposes. The specific listing for the approved uses of the chemicals as indicated in the Food Standards is provided in Table 2.2.

Table 2.2 Existing food standards for 24 chemicals

Food Standards	Number of chemicals
Permitted food additives	11
Generally permitted processing aid	2
Permitted processing aid as acidity regulator	3
Permitted processing aid for water	1
Permitted processing aid used in packaged water and in water used as an ingredient in other foods	4
Permitted bleaching, washing and peeling agent	5
Permitted processing aid for miscellaneous purposes	1
Permitted processing aid in other foods	2

Food Standards	Number of chemicals
Permitted processing enzymes of microbial origin	3
Miscellaneous additives permitted in processed foods	2

2.1.3 Chemicals currently listed in the Poisons Standard (the SUSMP)

The SUSMP, managed under the Therapeutic Goods Act, includes the classification of poisons into Schedules, setting the recommended level of control on the availability of the poisons to the public (TGA 2012). Twenty-four of the 69 chemicals are currently listed in various Schedules. Some of the listings are not specific to a particular chemical but exist for groups of substances to which the chemical may belong.

2.1.4 Chemicals currently listed in the HSIS

The HSIS includes information on the exposure standards and hazard classifications based on human health effects. The chemicals are classified in accordance with the Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008 (2004)] to ensure worker health and safety (Safe Work Australia 2013).

Of the 69 chemicals, 27 have existing hazard classifications for one or more human health endpoint/s and 25 have existing Australian exposure standards listed in the HSIS. There is an overlap of chemicals listed by the two control measures (i.e. classification and exposure standard). However, nine chemicals only had exposure standards assigned to them with no accompanying hazard classification.

The regulatory control status of the 69 chemicals at the time of assessment and the NICNAS recommended classifications to Safe Work Australia for other chemicals is provided in Table 2.3. The HSIS listing consists of chemicals with existing exposure standards and hazard classifications.

Table 2.3 Current and Australian regulatory controls of the chemicals and regulatory controls recommended by NICNAS

ID	CAS RN	Common name	ADWG	Food Std.	SUSMP	HSIS expos. Std.	HSIS current hazard class*	HSIS recomm. hazard class*
1	10043-35-3	Boric acid	✓	×	✓	×	D	
2	10043-52-4	Calcium chloride	✓	✓	×	×	B	
3	102-71-6	Triethanolamine	×	✓	✓	✓	×	B
4	107-21-1	Ethylene glycol	×	×	✓	✓	A	
5	107-22-2	Ethanedial	×	×	×	×	A, B, C	A†
6	108-10-1	Methyl isobutyl ketone	×	×	✓	✓	A, B, D	D†
7	111-30-8	Glutaraldehyde	×	×	✓	✓	A, B, C	
8	111-76-2	Butoxyethanol	×	×	✓	✓	A, B	
9	111-90-0	Diethylene glycol ethyl	×	×	×	×	×	

ID	CAS RN	Common name	ADWG	Food Std.	SUSMP	HSIS expos. Std.	HSIS current hazard class*	HSIS recomm. hazard class*
		ether						
10	112926-00-8	Precipitated silica	✓	✓	×	✓	×	
11	12008-41-2	Sodium borate	✓	×	×	×	×	D
12	1303-96-4	Sodium tetraborate	✓	×	✓	✓	D	
13	1305-62-0	Slaked lime	✓	✓	×	✓	×	B
14	1305-78-8	Lime	✓	✓	×	✓	×	B
15	1310-73-2	Caustic soda	✓	✓	✓	✓	B	
16	141-43-5	Ethanolamine	×	×	✓	✓	A, B	
17	144588-68-1	Sintered bauxite	×	×	×	×	×	B
18	14464-46-1	Cristobalite	✓	×	×	✓	×	D
19	14808-60-7	Quartz	✓	×	×	✓	×	D
20	15468-32-3	Tridymite	✓	×	×	✓	×	
21	26038-87-9	MEA polyborate	✓	×	×	×	×	D
22	26062-79-3	Polydimethyldiallylammonium chloride	×	×	×	×	×	
23	26172-55-4	Methylchloroisothiazolinone	×	×	×	×	×	A, B, C
24	2634-33-5	Benzisothiazolinone	×	×	×	×	A, B, C	
25	2682-20-4	Methylisothiazolone	×	×	×	×	×	A, B, C
26	497-19-8	Soda ash	✓	✓	✓	×	B	
27	52-51-7	Bronopol	×	×	×	×	A, B	A[‡]
28	55566-30-8	THPS	×	×	×	×	×	A, B, C
29	584-08-7	Potassium carbonate	×	✓	✓	×	×	B
30	64-02-8	Tetrasodium EDTA	✓	✓	×	×	A, B	B[†]
31	6410-41-9	Pigment Red 5	×	×	×	×	×	
32	64-17-5	Ethanol	×	✓	✓	✓	×	B
33	64-19-7	Acetic acid	×	✓	✓	✓	B	
34	64742-47-8	Deodorized kerosene	×	×	✓	×	D	

ID	CAS RN	Common name	ADWG	Food Std.	SUSMP	HSIS expos. Std.	HSIS current hazard class*	HSIS recomm. hazard class*
35	67-56-1	Methanol	×	×	✓	✓	A	
36	67-63-0	Isopropanol	×	✓	×	✓	B	
37	68187-17-7	C_{6-10} linear alkyl sulfate, ammonium salt	×	×	×	×	×	B
38	68439-45-2	C_{6-12} ethoxylated alcohols	×	×	×	×	×	B
39	68647-72-3	Sweet orange oil terpenes	×	×	×	×	×	B, C
40	75-57-0	Tetramethylammonium chloride	×	×	✓	×	×	A, B
41	7631-86-9	Amorphous silica	✓	✓	×	✓	×	
42	7647-01-0	Hydrochloric acid	✓	✓	✓	✓	A, B	
43	7681-52-9	Sodium hypochlorite	✓	✓	✓	×	B	
44	7722-84-1	Hydrogen peroxide	×	✓	✓	✓	A, B	
45	7727-54-0	Ammonium persulfate	×	✓	✓	✓	A, B, C	
46	7757-83-7	Sodium sulfite	×	✓	×	×	×	B
47	7758-19-2	Sodium chlorite	✓	✓	✓	×	×	B, D
48	7772-98-7	Sodium thiosulfate	×	×	×	×	×	
49	7775-27-1	Sodium persulfate	×	✓	✓	✓	A, B, C	
50	81741-28-8	Tributyltetradecyl phosphonium chloride	×	×	×	×	×	A, B
51	9012-54-8	Cellulase	×	✓	×	×	C	
52	9025-56-3	Hemicellulase	×	✓	×	×	×	C
53	91053-39-3	Calcined silica	✓	×	×	×	×	
54	90622-53-0	Alkanes, C_{12}-C_{26} branched linear	×	×	×	×	D	
55	CBI	2-Ethylhexanol heavies	×	×	×	×	×	A, B, D
56	CBI	Amine salt	×	×	×	×	×	B

ID	CAS RN	Common name	ADWG	Food Std.	SUSMP	HSIS expos. Std.	HSIS current hazard class*	HSIS recomm. hazard class*
57	CBI	Enzyme	×	✓	×	×	×	C
58	CBI	Ester alcohol	×	×	×	×	×	
59	CBI	Ethoxylated fatty acid I	×	×	×	×	×	A, B
60	CBI	Ethoxylated fatty acid II	×	×	×	×	×	
61	CBI	Ethoxylated fatty acid III	×	×	×	×	×	A, B
62	CBI	Fatty acids ester	×	×	×	×	×	
63	CBI	Inner salt of alkyl amines	×	×	✓	×	×	B
64	CBI	Organic acid salt	×	×	×	×	×	B
65	CBI	Organic sulfate	×	×	×	×	×	B
66	CBI	Polyamine	×	×	×	×	×	
67	CBI	Polymer with substituted alkylacrylamide salt	✓	✓	✓	✓	A, B, C, D	
68	CBI	Quaternary amine	×	×	×	✓	A,B	
69	CBI	Terpenes and terpenoids	×	×	×	×	×	B, C

*✓ – listed; × – not listed; * The specific hazard classifications are grouped into four with the following legend; A = acute oral, dermal, and / or inhalation toxicity; B = eye, skin and / or respiratory irritation; C = skin and / or respiratory sensitisation; D = repeat dose toxicity, carcinogenicity, mutagenicity, and / or reproductive toxicity; † – classification for another endpoint recommended in addition to current classifications; ‡ - recommended reclassification of an existing classification.*

The current classifications in the HSIS for 27 chemicals were confirmed by the hazard assessments of the chemicals.

2.2 Hazard classifications recommended by NICNAS

Based on the findings of the hazard assessments, the specification of regulatory controls for worker health and safety in the form of hazard classifications have been recommended by NICNAS to Safe Work Australia in accordance with the Approved Criteria for Classifying Hazardous Substances (NOHSC 2004) and the GHS (UNECE 2009).

Hazard classifications have been recommended by NICNAS for 30 chemicals that were not classified for worker health and safety in the HSIS at the time of assessment. Additional hazard classifications for different endpoints have also been recommended by NICNAS for 3 chemicals (ethanedial, methyl isobutyl ketone and tetrasodium EDTA) already listed in HSIS. Re-classification of an existing hazard classification for one endpoint was

recommended by NICNAS for one chemical (bronopol). A summary of the recommended classifications is presented in Table 2.3.

The model Work Health and Safety (WHS) Regulations mandate that the hazards of a chemical as determined by the GHS must be included by the manufacturer or importer of a hazardous chemical accurately in safety data sheets (SDS) and on labels. Listing in the HSIS provides information on the hazards of the chemical. Additionally, the WHS Regulations oblige industry to identify, assess and manage risks to health and safety associated with using, handling and storing a hazardous chemical in the workplace and that measures to control risks are reviewed and revised as required (Safe Work Australia 2016).

3 Conclusions

The 113 chemicals identified as being used in drilling and hydraulic fracturing of coal seam gas in Australia in the period 2010 to 2012 were assessed for their human health hazards. Following initial screening of the 113 chemicals using a validated NICNAS approach, 44 chemicals were found to be inherently of low concern for human health while 69 chemicals required further comprehensive assessment of the health hazards.

Of the 69 chemicals assessed:

- 27 had existing hazard classifications for one or more human health endpoint/s and 25 had existing Australian exposure standards as listed in the HSIS, noting that there is an overlap of chemicals that have both hazard classifications and exposure standards
- 3 had existing exposure standards but are not classified or recommended by NICNAS for classification for hazards
- 30 were not currently classified for worker health and safety and have been recommended by NICNAS for classification and listing in the HSIS
- 3 had existing hazard classifications for one or more human health endpoint/s and were recommended by NICNAS for additional classification for a different endpoint
- 1 had an existing hazard classification for a specific human health endpoint that was recommended for reclassification
- 9 were not currently listed in the HSIS and are not recommended by NICNAS for hazard classification.

NICNAS has recommended to Safe Work Australia that it add new classifications to the HSIS, or amend existing HSIS classifications for some chemicals, since HSIS classifications are based on the human health hazards of a chemical. Australian drinking water guidelines and food standards, by contrast, are based on the risk of a chemical. NICNAS therefore made no recommendations for the ADWG, Australian Food Standards, or the Poisons Standard.

Human health risk is a product of the hazard of a chemical and the level of exposure of a person to the chemical. In the next step, predicted environmental exposure of humans to the 69 chemicals were modelled and quantified. The human hazard assessments were then integrated with the exposure assessments to characterise the human health risks arising from the use of the 69 chemicals in coal seam gas extraction in Australia, with the results being presented in a human health risk assessment report.

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Appendix A – Individual human health hazard assessments

The individual human health hazard assessments of the 69 chemicals are included in Appendix A to this report [published separately].