2-Propenoic acid, butyl ester: Human health tier II assessment

18 September 2014

CAS Number: 141-32-2

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Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multitiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

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Chemical Identity

Synonyms	acrylic acid, butyl ester butyl 2-propenoate n-butyl acrylate 2-propenoic acid, butyl ester butyl acrylate	
Structural Formula	H ₂ C CH ₃	
Molecular Formula	C7H12O2	
Molecular Weight (g/mol)	128.17	
Appearance and Odour (where available)	Clear, colourless liquid with a strong, fruity odour.	
SMILES	C(=O)(C=C)OCCCC	

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

The chemical has reported site-limited use including as a:

- synthetic intermediate/laboratory chemical; and
- monomer used in the synthesis of homopolymers and copolymers.

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume of 10000-99999 tonnes.

The Australian safety data sheets (SDS) for the chemical indicate its use as a component of paints (10–29 %), fillers (10–29 %), coatings (0–1 %), and resins (0.6–1 %). The SDSs indicate specific uses of paints for road markings and fillers for concrete repair compounds.

International

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The following international uses have been identified through the Substances and Preparations in the Nordic countries (SPIN) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use as a binding agent. However, the chemical is not listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011).

The chemical has reported domestic use including in:

- adhesives and binding agents;
- corrosion inhibitors;
- fillers;
- paints, lacquers and varnishes;
- surfactants;
- cleaning and washing agents; and
- colouring agents.

Although the chemical has reported domestic uses in the SPIN database, it should be noted that SPIN does not distinguish between direct use of the chemical or use of the materials that are produced from chemical reactions involving the chemical.

The chemical has reported commercial use including:

- in construction materials;
- in dust binding agents;
- in hydraulic fluids and additives;
- as a process regulator;
- in reprographic agents; and
- as a solvent.

The chemical has reported site-limited use including:

- in impregnation materials; and
- as a monomer in the synthesis of polymers.

Restrictions

Australian

No known restrictions have been identified for the chemical.

International

The chemical is listed on the following (Galleria Chemica):

Plastics materials and articles intended to come in contact with food. The chemical may be used with a specific migration limit (SML) of 22 mg/kg in food packaging, under Annex I of the European Commission Regulation (EU) No 10/2011 of 14 January 2011.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Xi; R43 (skin sensitiser)

Exposure Standards

Australian

The chemical has an exposure standard of 5 mg/m³ (1 ppm) time weighted average (TWA) and 26 mg/m³ (5 ppm) short-term exposure limit (STEL).

International

The following exposure standards are identified (Galleria Chemica).

TWA:

- 5 mg/m³ (1 ppm) in the UK;
- 10–11 mg/m³ (2 ppm) in Austria, Belgium, Bulgaria, Canada, China, Columbia, the Czech republic, Denmark, Finland, Germany, Hungary, Iceland, Ireland, Italy, Korea, Latvia, Luxembourg, Malaysia, Malta, the Netherlands, the EU, Nicaragua, Norway, Peru, Poland, Portugal, Russia, Spain, Switzerland, Turkey, Slovakia, Serbia and Venezuela; and
- 50–55 mg/m³ (10 ppm) in Croatia, Egypt, Greece, Indonesia, Mexico, New Zealand, Sweden, Singapore, South Africa, the UAE and the US.

Short-term exposure limits (STEL):

- 22–30 mg/m³ (4–6 ppm) in the Czech republic, Poland, Switzerland and the UK;
- 53 mg/m³ (10 ppm) in Austria, Belgium, Bulgaria, Finland, Hungary, Iceland, Ireland, Korea, Latvia, the Netherlands, Malta, Luxembourg, the EU, Peru, Turkey, Serbia and Spain; and
- 80 mg/m³ (15 ppm) in Sweden.

Health Hazard Information

Toxicokinetics

The chemical is readily absorbed by oral, dermal and inhalation exposure and rapidly metabolised. After oral administration in rats, the chemical is metabolised by two main pathways. The majority is hydrolysed by carboxylesterase to yield acrylic acid (CAS No. 79-10-7) and 1-butanol (CAS No. 71-36-3), while a smaller portion is conjugated with glutathione to form thioesters. The excretion in rats was mainly as expired CO₂ (75 % within two hours), with the remainder eliminated via urine (10 %) and faeces (2 %) (OECD 2004; REACH).

Half–lives are reported for the chemical in rats, mice, rabbits, guinea pigs and in human blood as 3.7, 4.3, 1.6, 2.3 and 37.6 minutes, respectively. The extended half–life observed in humans is attributed to the lack of alkyl ester specific carboxylesterases in human plasma compared with rodents, with slower hydrolysis by butyryl cholinesterases (REACH).

Acute Toxicity

Oral

The chemical has low acute oral toxicity based on animal studies.

The median lethal dose (LD50) in rats is greater than 2000 mg/kg bw. Observed sublethal effects included loss of appetite, rapid breathing, piloerection and staggered gait (OECD, 2004; REACH).

Dermal

The chemical has low acute dermal toxicity based on animal studies.

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The dermal LD50 in rats and rabbits is greater than 2000 mg/kg bw. Observed sublethal effects included erythema and necrosis of the skin (OECD, 2004; REACH).

Inhalation

The chemical has moderate acute inhalation toxicity in animals. Based on the median lethal concentrations (LC50) reported, a hazard classification is warranted.

In an acute inhalation toxicity study equivalent to the Organisation for Economic Cooperation and Development test guideline (OECD TG) 403, Sprague Dawley (SD) rats (n = 10/sex/dose) were exposed to vapours of the chemical at 2.7, 3.6, 5.0, 6.8, 8.1, 12.1 or 16.0 mg/L for four hours. Mortalities occurred at 6.8 (1/20 rats), 8.1 (4/20 rats), 12.1 (13/20 rats) and 16.0 mg/L/4-hours (10/10 rats) dose groups. An LC50 of 10.3 mg/L/4-hours was determined (OECD, 2004; REACH).

Another study (equivalent to OECD TG 403) exposed SD rats (n = 10/sex/dose) to vapours of the chemical ranging from 5.9–24.2 mg/L for four hours. An LC50 of 11.9 mg/L/4-hours was calculated, with clinical signs of strong irritation to mucous membranes and panting being observed (OECD, 2004; REACH).

Corrosion / Irritation

Respiratory Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (Safe Work Australia). The data available from a repeated dose inhalation study in rats support this classification.

A repeated dose inhalation toxicity study (13 weeks) in SD rats indicated strong irritation of the nasal mucosa, with histopathological changes from 0.57 mg/L (see **Repeat dose: Inhalation**) (OECD, 2004).

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The available data support this classification.

The undiluted chemical (0.5 mL) was applied via an occlusive patch to the unabraded skin of New Zealand White rabbits (n = 6) for a four-hour period (non-guideline study). The chemical produced mean scores (at 24, 48 and 72 hours) of 3.3/4 for erythema and 3.1/4 for oedema. The effects were not fully reversible within 72 hours (REACH).

In another study, the chemical was applied to unabraded skin of Vienna rabbits (n = 2), resulting in severe erythema (3.9/4) and oedema (2.9/4) after 15 minutes of exposure. After eight days, erythema was not fully reversible, but the oedema was reversible (OECD, 2004; REACH).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The limited data available support this classification.

In a poorly-documented study, the undiluted chemical (0.5 mL) was applied to the eyes of rabbits (n = 5, one eye per animal). No effects were observed in one of the animals, while moderate effects were observed in two rabbits and severe effects (iritis) observed in the remaining two rabbits (OECD, 2004). Irritation scores were not available.

Sensitisation

Skin Sensitisation

The chemical is classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in HSIS (Safe Work Australia). The available data support this classification.

In a local lymph node assay (OECD TG 429), female CBA mice (n = 4/dose) were treated with the chemical (in acetone/olive oil at 4:1 v/v) at concentrations of 0.5, 1.0, 2.5, 5.0 and 10 %. The chemical was determined to be a weak skin sensitiser based on the effective concentration needed to produce a three-fold increase in lymphocyte proliferation (EC3) value of 11.2 % (Dearman et al., 2007; REACH)

In a guinea pig maximisation test, female Himalayan guinea pigs (n = 10) were induced with the chemical in a 2:1 mix of methyl ethyl ketone/peanut oil at a concentration of 0.5 M (7 %, intradermal) and 1 M (14 %, topical) on days 0 and 7, respectively and challenged with the maximum non-irritant

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concentration of 0.1 M (1.4 % the chemical). Seven out of 10 animals showed a positive skin sensitisation reaction upon challenge and re-challenge (OECD, 2004; REACH).

Observation in humans

Positive skin sensitisation results have been observed in several human patch tests. In one study, 82 patients who were suspected to have 'occupational acrylic sensitisation' were patch tested with 1 % of the chemical in petrolatum. Two of the patients showed sensitisation to the chemical (OECD, 2004).

Two other poorly-documented studies reported 1/22 patients (no exposure concentration available) and 1/9 patients (exposed to 0.1 % of the chemical in petrolatum) showed positive skin reactions in patch tests with the chemical (REACH).

Repeated Dose Toxicity

Oral

Based on the data available, the chemical is not considered to cause serious damage to health from repeated oral exposure.

In a 13-week repeated dose oral toxicity study (equivalent to OECD TG 408), Fischer 344 rats (n = 15/sex/group) were administered the chemical at concentrations of 0, 0.016, 0.10 or 0.12 % w/v in drinking water (equivalent to 0, 12, 73 or 84 mg/kg bw in males and 0, 15, 91, 111 mg/kg bw in females). No treatment-related effects were observed up to the highest concentrations tested. The no observed adverse effect levels (NOAELs) of 84 and 111 mg/kg bw/d for male and female rats, respectively, were reported. A satellite group (n = 5/sex) was administered the chemical at 150 mg/kg bw/d via oral gavage, over the 13 weeks. The dose of 150 mg/kg bw/d was indicated to be the lowest observed adverse effect level (LOAEL), based on increased liver weight compared with the control animals (OECD, 2004; REACH).

Dermal

Based on the data available, the chemical is not considered to cause serious damage to health from repeated dermal exposure.

In a carcinogenicity study, the chemical was applied to the dorsal skin of C3H/HeJ mice (n = 10/sex/group) at 8 mg/kg bw/d, three times per week for their lifetime (mean duration 503 days). No systemic effects were observed related to the treatment and there was no significant difference in mortality rates between the treated and control groups (see **Carcinogenicity**) (OECD, 2004; REACH).

Inhalation

Based on the data available, the chemical is not considered to cause serious health effects from repeated inhalation exposure.

In a 13-week repeated dose inhalation toxicity study (equivalent to OECD TG 413), SD rats (n = 20/sex/group) were exposed to the chemical vapour at concentrations of 0, 0.11, 0.57, 1.11 or 2.86 mg/L (0, 21, 108, 211 or 546 ppm) for six hours per day, five days per week. The lowest observed adverse effect concentration (LOAEC) for systemic effects was reported to be 1.11 mg/L/6-hours/day based on decreased body weight and changes in clinical chemistry parameters in females. Local effects included strong irritation of the eyes and nasal mucosa. Histopathological changes of the nasal mucosa were also observed from 0.57 mg/L (OECD, 2004; REACH).

Genotoxicity

Based on the results of available in vitro and in vivo genotoxicity studies, the chemical is not considered to be genotoxic.

The chemical gave mixed results in several in vitro genotoxicity assays:

- negative results in a bacterial reverse mutation assay (Ames test) with Salmonella typhimurium strains TA 98, 100, 1535, 1537 and 1538, with or without metabolic activation, up to 10 mg/plate (OECD, 2004);
- negative results in a mammalian cell gene mutation assay that used Syrian hamster embryo fibroblasts, without metabolic activation (OECD, 2004);
- negative results in several mammalian cell gene mutation assays that used Chinese hamster ovary cells, with or without metabolic activation (OECD, 2004; REACH);
- positive results in a mammalian cell sister chromatid exchange assay that used Chinese hamster ovary cells, with or without metabolic activation at concentrations of up to 502.6 μg/L (OECD 2004); and
- positive results in two mammalian gene mutation assays with the chemical at concentrations between 20–40 µg/mL, using mouse lymphoma (L5178Y) cells, with or without metabolic activation (REACH).

The chemicals gave negative results during in vivo genotoxicity assays:

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1191

- a chromosome aberration study in bone marrow cells of SD rats (n = 10/sex/dose) exposed to the chemical vapour at 820 ppm (4.3 mg/L) for six hours per day for four days (equivalent to OECD TG 475) (OECD, 2004; REACH); and
- a chromosome aberration study in bone marrow cells of Chinese hamsters (n = 10/sex/dose) (equivalent to OECD TG 475) exposed to the chemical vapour at 817 ppm (4.28 mg/L) for four days (six hours for three days and five hours on the remaining day) (OECD, 2004; REACH).

Carcinogenicity

Based on the available data, the chemical is not considered to be carcinogenic via inhalation or dermal exposure.

The International Agency for Research on Cancer (IARC) has determined that the chemical is 'not classifiable as to its carcinogenicity to humans' (Group 3), based on 'no epidemiological data relevant to the carcinogenicity' of the chemical, and 'inadequate evidence in experimental animals for the carcinogenicity' of the chemical (IARC, 1999).

In a two-year combined chronic inhalation toxicity and carcinogenicity study (OECD TG 453), SD rats (n = 86/sex/group) were exposed to vapours of the chemical at concentrations of 0, 15, 45 or 135 ppm (0, 0.086, 0.26 or 0.77 mg/L) for six hours per day, five days per week. No neoplasms were observed at the highest concentration tested, thus a no observed adverse effect concentration (NOAEC) greater than 0.77 mg/L was established for carcinogenicity (OECD, 2004; REACH).

In a lifetime study (mean of 503 days), male C3H/HeJ mice (n = 40) were dermally treated with the chemical (1 % solution in acetone) at 8 mg/kg bw/d, for three times per week. No systemic effects related to treatment were observed and the only neoplasm in the treatment group was a fibrosarcoma, which was also observed in control animals. The NOAEC for carcinogenicity was greater then 8 mg/kg bw/d (REACH).

The main hydrolysis products, 2-propenoic acid (NICNASa) and 1-butanol (NICNASb), were also not considered carcinogenic.

Reproductive and Developmental Toxicity

The chemical is not considered to have reproductive or developmental toxicity.

Although no reproductive toxicity studies on the chemical were available, a structurally related compound, methyl acrylate (CAS No. 96-33-3) up to 2.33 mg/L concentration showed no reproductive toxicity in a two-generation study (OECD TG 416) (REACH). In a 13-week repeated dose toxicity study, SD rats (n = 20/sex/group) exposed to butyl acrylate vapour at 0, 21, 108, 211 or 546 ppm (0, 0.11, 0.57, 1.11 or 2.86 mg/L/day) for six hours per day, five days per week, showed no effects in the uterus, ovaries, seminal vesicles, prostate, epididymis or testes up to the highest concentration tested. The NOAEC was reported to be 2.86 mg/L (OECD, 2004; REACH).

There are several developmental toxicity studies with the chemical. In a prenatal developmental toxicity study (OECD TG 414), pregnant SD rats (n = 20/group) were exposed to the chemical at concentrations of 0, 100, 200 or 300 ppm (0, 0.52, 1.02 or 1.57 mg/L/day) during gestation days (GD) 6–20. An LOAEC of 0.52 mg/L for maternal toxicity was reported based on decreased body weight gain observed in all treatment groups. An NOAEC of 0.52 mg/L for foetotoxicity was reported based on decreased foetal body weight observed in the 1.05 and 1.57 mg/L treatment groups (7–8 % and 26–28 %, respectively). No teratogenic effects were observed (REACH).

In a study with pregnant CD1 mice (n = 25–30/group) administered the chemical by oral gavage doses of 0, 100, 1000, 1500, 2000, 2500, 3000 or 4000 mg/kg bw/day during GD 6–15, a NOAEL of 100 mg/kg bw was determined for maternal toxicity based on maternal mortalities and reduce weight gain. A NOAEL of 1000 mg/kg bw/day for developmental toxicity was established based on decreased foetal body weight. The NOAEL for teratogenicity was 2000 mg/kg bw/day, based on soft tissue and skeletal abnormalities (cleft palate, exencephaly, fused arches and fused ribs) at higher doses (OECD, 2004).

No developmental toxicity effects were observed in Himalayan rabbits exposed to the chemical vapours (OECD TG 414) up to 44.2 ppm (155.6 mg/m³) for six hours on gestation days 6–28 (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- local effects—skin sensitisation; skin, eye and respiratory irritation; and
- systemic acute effects—from inhalation exposure.

Public Risk Characterisation

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The chemical is not listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011). However, the SPIN database indicates it to be used as a binder in cosmetics. SPIN does not distinguish between direct use of the chemical or use of the materials that are produced from chemical reactions involving the chemical. Therefore, cosmetic use of the chemical with potential public exposure is not expected.

According to some Australian SDSs, the chemical is expected to be used in specific paints and fillers in Australia, at concentrations up to 29 %. However, use of these products in a domestic setting is not expected.

Given the uses identified in Australia, it is unlikely that the public will be exposed to the chemical. Although the public might come into contact with articles/coated surfaces containing the chemical, it is expected that the chemical will be bound within the article/coated surface and hence will not be bioavailable. Therefore the risk to the public is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical might occur, particularly where manual or open processes are used. Worker exposure to the chemical at lower concentrations can also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical health effects (skin sensitisation and irritation), the chemical can pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls. The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation section**).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Harmful by inhalation (Xn; R20)	Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)

^a Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

^b Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

* Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace*—Code of practice available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals*— *Code of practice* and *Labelling of workplace hazardous chemicals*—*Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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