Ethanol, 2,2'-iminobis-: Human health tier II assessment

12 September 2013

CAS Number: 111-42-2

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered 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.

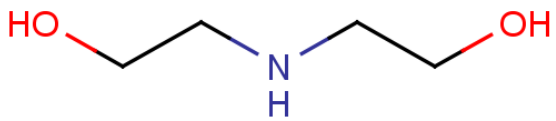
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	diethanolamine (DEA) 2,2'-iminobisethanol 2,2'-dihydroxydiethylamine diolamine
Structural Formula	
Molecular Formula	C4H11NO2
Molecular Weight (g/mol)	105.14
Appearance and Odour (where available)	Colourless crystals or a white syrupy liquid with a mild ammonical odour.
SMILES	C(O)CNCCO

Import, Manufacture and Use

Australian

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume of 1000 – 9999 tonnes. The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information:

The chemical has reported domestic use including as a:

- softening agent in cleaning and washing products.

The chemical has reported commercial use including:

- in construction material additives; and
- as a photochemical additive.

The chemical has reported site-limited use including in the:

- manufacture of other chemicals;
- manufacture of paints and lacquers;
- leather processing industry; and
- pulp and paper industry.

Cosmetic use of the chemical was identified in the 2002 High Volume Industrial Chemicals List (HVICL).

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported domestic use including:

- as a softening agent in a range of household soaps, detergents and car wash products; and
- in caulk/sealant removers.

The chemical has reported commercial use including:

- as a surfactant and corrosion inhibitor;
- in automotive products;
- photographic solutions;
- paints, lacquers and varnishes; and
- cutting fluids.

The chemical has reported site-limited use including:

- in the manufacture of other chemicals;
- as a fuel additive;
- as a laboratory reagent;
- in the textile industry;
- in oil refineries to remove hydrogen sulfide gas; and
- in pH regulation.

Restrictions

Australian

This chemical is listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in Schedules 5 and 6.

Schedule 5 : Diethanolamine (excluding its salts and derivatives) in preparations containing 20 % or less of diethanolamine except in preparations containing 5 % or less of diethanolamine.

Schedule 5 chemicals are labelled with 'Caution'. These are substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Schedule 6: Diethanolamine (excluding its salts and derivatives) except:

(a) when included in Schedule 5; or

(b) in preparations containing 5 % or less of diethanolamine.

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label.

International

According to the European Union Council Directive 76/768 EEC, the use of diethanolamine in cosmetics is prohibited in the EU. Diethanolamine and its salts (Secondary alkyl- and alkanolamines and their salts) are listed in Annex II/411 (List of substances prohibited in cosmetic products) (CosIng). However, fatty acid dialkylamides and dialkanolamides are listed in Annex III/60 which allows them in cosmetics with the following conditions:

- maximum secondary amine content of 0.5 %;
- do not use with nitrosating systems;
- maximum secondary amine content 5 % (applies to raw materials);
- maximum nitrosamine content: 50 µg/kg; and
- keep in nitrite-free containers.

In Canada, dialkanoalamines (including, but not limited to diethanolamine (DEA) (111-42-2) and diisopropanolamine (DIPA) (110-97-4)) are prohibited for use in cosmetics as per the Health Canada List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient "Hotlist").

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):

Xn; R22 (Acute toxicity)

Xi; R38/41 (Irritation)

Xn; R48/22 (Repeated dose toxicity)

Exposure Standards

Australian

The chemical has an exposure standard of 13 mg/m³ (3 ppm) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 2 - 15 mg/m³ (0.46 – 3 ppm) in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

Toxicokinetics

Male Fischer 344 (F344) rats were orally administered radiolabelled (2 - 200 µCi) diethanolamine (DEA) (0.7 - 200 mg/kg bw) which was totally absorbed within 24 hours from the gastrointestinal tract. After 48 hours, up to 57 % of the chemical was distributed to various tissues (adipose, blood, brain, heart, kidney, liver, lung, muscle, skin and spleen), the majority being detected in the kidney and liver (REACH). Single oral doses of the chemical were excreted predominantly as unchanged diethanolamine, with 20-30 % of the orally administered dose excreted primarily in urine and faeces (REACH). The toxicokinetic profile was similar for a single intravenous dose (OECD, 2008).

Dermally, male $B6C3F_1$ mice administered 8 - 80 mg/kg bw showed a dose dependent increase in absorption (25 - 60 %) of the chemical within 48 hours. The distribution of the chemical was similar to that in the rat study (highest concentration of the chemical was present in the liver and kidney) (REACH). In vitro studies comparing skin absorption of the chemical (37 % aqueous solution) in mouse, rat, rabbit and human skin showed that skin penetration was the greatest in mice (6.7 %) followed by rabbits (2.8 %), rats (0.56 %) and humans (0.23 %) (OECD, 2008).

Repeated dose oral administration studies showed a similar absorbtion and distribution profile to the acute administration study. Metabolism was also similar to when the chemical was acutely administered, but small proportions of N-methyl-DEA, N,N-dimethyl-DEA and DEA-phosphates were also found (OECD, 2008).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase ‘Harmful if swallowed’ (Xn; R22) in HSIS (Safe Work Australia). The available data support this classification.

The reported oral median lethal dose (LD50) values in rats ranged from 780 - 3540 mg/kg bw (OECD, 2008). In one study male Sprague Dawley (SD) rats administered a single oral dose of aqueous DEA (100 – 6400 mg/kg bw) resulting in 90 % mortality at the highest dose. Doses greater than 100 mg/kg bw resulted in an increase in liver weight. An increase in the relative kidney weight was observed at doses greater than 1600 mg/kg bw. Clinical chemistry changes were reported for the liver at doses greater than 200 mg/kg bw and for the kidney at greater than 400 mg/kg bw (OECD, 2008).

Dermal

The chemical was of low acute toxicity in animal tests following dermal exposure. The median lethal dose (LD50) in rabbits is greater than 12000 mg/kg bw (IUCLID, 2000).

Inhalation

The chemical was of low acute toxicity in animal tests following inhalation exposure. The median lethal concentration (LC50) in rats is 6.4 mg/L. The available data do not warrant hazard classification.

Acute inhalation exposure to the chemical for 1.5 – 4 hours at concentrations between 30 – 1476 ppm (0.13 - 6.4 mg/L) caused mortality in 5/8 rats after 105 minutes of exposure to 6.4 mg/L. Exposure to 3.35 mg/L (768 ppm) for up to 4 hours resulted in no mortality. It was reported that the exposure was to vapours or aerosols (most likely at the higher concentration). Observed sub-lethal effects included lethargy, increased breathing, increased blood pressure, congestion in the lung and discolouration in the kidney and thymus (REACH; OECD 2008).

Observation in humans

It is reported that the fatal oral dose of the chemical is 20g in humans (HSDB).

Corrosion / Irritation

Respiratory Irritation

Refer to '**Repeat Dose Toxicity - Inhalation**'.

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 chemical on unabraded rabbit skin produced skin irritation after 1 - 15 minutes and marked irritation after 20 hours. Over 72 hours, erythema increased and oedema decreased (REACH). After 20 hours of exposure the mean Draize scores for erythema and oedema formation were 2 and 1.33, respectively. While the Draize scores for erythema and oedema returned to normal after 8 days, severe desquamation of the skin persisted.

The chemical is also reported to cause ulceration, inflammation and hyperkeratosis following repeated exposure (Refer to **Repeat Dose Toxicity - Dermal**).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). The available data support this classification.

In an eye irritation study in Vienna White rabbits, 0.05 mL of the chemical was instilled into the rabbit’s eyes and observed for eight days. The chemical caused signs of severe irritation consisting of superficial corrosion, corneal opacity, conjunctival bleeding, conjunctivitis and oedema (OECD, 2008; REACH). Extensive corrosion was evident at the end of the observation period.

In a further study, 0.1 g of the chemical was applied into the conjunctival sac of New Zealand White rabbits. This resulted in strong irritation of the cornea, iris and conjunctiva, which did not completely resolve over seven days of observation (OECD, 2008).

Sensitisation

Skin Sensitisation

The chemical was not found to induce dermal sensitisation in the Guinea pig maximization test conducted according to OECD Test Guideline (TG) 406 (OECD, 2008).

Repeated Dose Toxicity

Oral

The chemical is classified as hazardous with the risk phrase 'Harmful : Danger of serious damage to health by prolonged exposure if swallowed' (Xn; R48/22) in HSIS (Safe Work Australia). The available data support this classification.

In a 90 day oral gavage study conducted similarly to OECD TG 408 in F344 rats, lowest observed adverse effect levels (LOAEL) of 320 and 160 ppm (equivalent to 25 and 14 mg/kg bw/day, respectively) was reported in male and female rats, respectively. These were the lowest doses tested. Mortality was observed in males (2/10 animals) at the highest dose (5000 ppm) before the completion of the study (REACH; OECD, 2008). Signs of toxicity were observed across all dose groups (160 - 2500 ppm), and included tremors, extreme weight loss, abnormal posture and a dose dependent increase in microcytic anaemia. Dose related (≥ 320 ppm in males and ≥ 160 ppm in females) changes in kidney weights were associated with an increase in nephropathy and renal cell necrosis. Dose related (≥ 320 ppm in males and ≥ 630 ppm in females) increase in liver weight was associated with a moderate increase in serum bile acid concentration (REACH; OECD, 2008).

Dermal

Based on treatment-related effects reported with a LOAEL of 32 and 80 mg/kg bw/day in rat and mouse studies, respectively, the chemical is considered to cause serious damage to health from repeated oral exposure. The available data warrant a hazard classification (refer **Recommendation** section).

In a 90 day dermal application study conducted similarly to OECD TG 411 in F344 rats, a LOAEL of 32 mg/kg bw/day was reported in male and female rats. Mortality occurred in one male and two female rats administered the highest dose of 500 mg/kg bw/day (REACH; OECD, 2008). Ulceration, inflammation, hyperkeratosis, and acanthosis occurred at all administered doses (32 - 500 mg/kg bw/day). Other signs of toxicity included reductions in body weight gain, anaemia, renal function changes and liver weight increases. Demyelination in the brain, nephropathy and renal tubular necrosis were also observed (REACH; OECD, 2008).

In a similar study conducted similarly to OECD TG 411 in B6C3F$_1$ mice, a LOAEL of 80 mg/kg bw/day was reported in male and female mice. Effects on the skin were noted at all doses (80 - 1250 mg/kg bw/day) and consisted of acanthosis at the lower doses and a dose-dependent increase in ulcerations, inflammation and hyperkeratosis at higher dose levels (630 and 1250 mg/kg bw/day in males and females, respectively) (REACH; OECD, 2008). Further signs of toxicity included dose dependent increases in liver and kidney weights. The increase in liver weight was associated with hepatocellular changes consisting of enlarged hepatocytes and, at the higher dose levels, the presence of multinucleated, giant hepatocytes. Liver damage (hepatocellular necrosis) was observed in male mice only (REACH; OECD, 2008).

Inhalation

Based on the available data no adverse systemic toxicity was evident. Local effects were observed at a lowest observed adverse effect concentration (LOAEC) of 0.15 mg/L in one study. The available data do not warrant a hazard classification for repeated dose inhalation toxicity. However, a classification for respiratory irritation is warranted (refer **Recommendation** section).

In a 90 day inhalation study conducted according to OECD TG 413 in Wistar rats, a LOAEC of 0.15 mg/L was reported in male and female rats. Local inflammation (focal squamous metaplasia and hyperplasia) was evident in the larynx (0.15 mg/L) and trachea (0.4 mg/L) in a concentration dependent manner (REACH, SIDS, 2008). Marginal increases in liver weight and serum alkaline phosphatase levels occurred at the mid - high doses (0.15 and 0.4 mg/L, respectively), although, no histopathological changes were noted. In females, erosions of the glandular stomach occurred in a dose dependent manner (0.15 mg/L and 0.4 mg/L) (REACH; OECD, 2008).

A further study conducted according to OECD TG 413 in male and female Wistar rats using lower doses (0.0015, 0.003 or 0.008 mg/L) showed similar local irritation effects (focal squamous metaplasia) after 90 days of exposure. After 90 days of exposure to the chemical, a group of 10 animals were given three months of recovery. At the end of the recovery period, no treatment related systemic effects were observed, indicating reversibility in the laryngeal epithelium up to the highest dose administered (0.008 mg/L) (REACH, OECD, 2008).

Genotoxicity

The chemical tested negative in several in vitro (Ames test with and without metabolic activation, reverse mutation assay, cytogenic assay and the mouse lymphoma assay) and in vivo (micronucleus assay and the alkaline elution assay) tests for gene mutation and clastogenicity (OECD, 2008).

Carcinogenicity

The International Agency for Research on Cancer (IARC) has classified the chemical as ‘Probably carcinogenic to humans’ (Group 2B), based on inadequate evidence for carcinogenicity in humans, and sufficient evidence for carcinogenicity based on animal testing. However, considering that the effects observed were liver tumours in mice (B6C3F1) known to have a higher spontaneous liver tumour incidence, further assessment is recommended prior to hazard classification for carcinogenicity.

National Toxicology Program (NTP) studies:

In a two year study conducted in male and female $B6C3F_1$ mice, the dermal administration of the chemical (40 - 160 mg/kg bw/day, five days a week) significantly reduced survival in female mice only across all dose groups. Compared with the control animal group, the incidence of hepatocellular adenomas and carcinomas was significantly increased across all dose groups in male and female mice. The incidence of hepatoblastoma was increased in male mice in the mid (80 mg/kg bw/day) and high (160 mg/kg bw/day) dose groups. Furthermore, male mice had a significant increase in renal tubule adenomas compared with the control animal group (NTP, 1999).

In F344/N rats, dermal administration (16 - 64 mg/kg bw/day in males and 8 - 32 mg/kg bw/day in females) of the chemical for two years did not affect survival. Body weights were lower in male and female rats administered the highest dose of the chemical. There was no increase in the tumour incidence of F344/N rats in this study (NTP, 1999).

Genetic studies:

Female Tg.AC mice which were administered (5 - 20 mg/mouse) the chemical five times a week for 20 weeks did not affect survival. In contrast to the positive controls, there was no significant increase in the incidence of skin tumours (multiple papillomas) (IARC, 2012).

Human exposure:

Occupational exposure to the chemical through metal-working fluids has been reviewed by the International Agency for Research on Cancer (IARC), which concluded that the majority of studies included mixtures of chemicals containing DEA, therefore making it difficult to distinguish the carcinogenic effect of DEA alone from that of the complex mixture. No studies were identified that evaluated human cancer associated with the use of personal care products that contain diethanolamine (IARC, 2012).

Nitrosamine formation:

Nitrosamine formation has been highlighted as a matter of concern for this chemical under certain conditions, and for this reason it has been banned for use in cosmetics in the EU. In the NTP study conducted in mice, nitrosamine formation was ruled out due

to the conditions of the study.

Reproductive and Developmental Toxicity

While there appears to be some concern for reproductive and developmental toxicity, this occurs at doses well above the LOAEL determined for systemic toxicity. A Tier III assessment is recommended to investigate whether classification is warranted.

Reproductive

In a study conducted according to OECD TG 413, male and female Wistar rats were exposed to the chemical via inhalation (0.015, 0.15 or 0.4 mg/L) for five times a week for 90 days. Reproductive effects were reported at the highest concentration (0.4 mg/L) which included testicular atrophy and slight atrophy of the prostate. No changes were observed in female rats (OECD, 2008). Other adverse effects observed were of a local nature (refer to **Repeated Dose Toxicity - Inhalation**).

In a 13 week study, the chemical was orally administered to F344 rats via drinking water (320, 630, 1250, 2500 or 5000 ppm for males or 160, 320, 630, 1250, or 2500 ppm for females). Mortality was observed in 2/10 male rats in the high dose group (5000 ppm). Signs of reproductive toxicity included decreases in testis and epididymis weights (≥ 1250 ppm). Testicular degeneration was observed in all animals administered the high dose (5000 ppm) and in 3/10 males at the 2500 ppm dose level. These effects were associated microscopically with degeneration of seminiferous epithelium as well as hypospermia and reduced sperm motility at doses ≥ 2500 ppm. No effect on the reproductive organs of the females was noted. The NOAEL for reproductive effects in males was 630 ppm (48 mg/kg bw/day) (OECD, 2008). Non-reproductive adverse effects observed in this study are discussed in the **Repeated Dose Toxicity - Oral** section.

No reproductive toxicity in males or females was reported after the dermal administration of the chemical (32, 63, 125, 250 or 500 mg/kg bw/day) to F344 rats for 13 weeks (OECD, 2008). No morphological effect in male or female reproductive organs, sperm parameters or vaginal cytology was noted (OECD, 2008).

Developmental

A study was conducted in accordance with OECD TG 414 using female Wistar rats exposed to the chemical for six hours a day from day 6-15 post coitum via inhalation at concentrations ranging from 0.01, 0.05 or 0.2 mg/L. Maternal toxicity substantiated by clinical symptoms of vaginal haemorrhage was observed at the highest dose administered (OECD, 2008). At the highest dose administered, foetuses were born with skeletal variations, although this was not considered to be related to inhalation of the chemical. Considering the maternal mortality associated with the highest dose administered in this study, the no observed adverse effect concentration (NOAEC) for teratogenicity was determined to be > 0.2 mg/L (OECD, 2008).

In a dose finding study conducted by the NTP, the chemical was administered to female CD-1 mice at doses of 200, 380, 720, 1370 or 2605 mg/kg bw/day (on days 6 - 15 through gestation and on day 17). Mortality was observed at doses ≥720 mg/kg bw/day and all animals dosed at ≥1370 mg/kg bw/day died prematurely (OECD, 2008). In the second part of the study, 450 mg/kg bw/day was administered under similar conditions. This dose did not affect maternal mortality, litter size, birth weight of pups, but decreased the number of viable litters, the percentage survival of pups and the weight gained by the pups. It was concluded that the chemical was positive in the Chernoff/Kavlock preliminary developmental toxicity test (OECD, 2008).

In a further study, 12 Sprague Dawley (SD) rats were orally administered the chemical at dose levels of 50, 125, 200, 250 or 300 mg/kg bw/day on gestation days 6 – 19. All females administered 300 mg/kg bw/day had to be euthanised early due to excessive toxicity. At 125 mg/kg bw/day, maternal absolute kidney weights were increased. The NOAEL for maternal toxicity was 50 mg/kg bw/day in this study. Developmental toxicity consisted of a significant increase in postnatal mortality on postnatal days 0 - 4 at ≥ 125 mg/kg bw/day and an increase in post implantation mortality at ≥ 200 mg/kg bw/day. Pup body weight was reduced at doses ≥ 200 mg/kg bw/day, with female pups more affected than males. The NOAEL for postnatal developmental toxicity was 50 mg/kg bw/day (OECD, 2008).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic acute effects (acute toxicity by the oral route of exposure) and local effects (skin, eye and respiratory irritation). The chemical may also cause harmful effects following repeated exposure through oral and dermal routes. The available data are not sufficient to draw conclusions concerning carcinogenicity or reproductive toxicity at the Tier II level.

Public Risk Characterisation

In Australia, the chemical is known to be used in washing and household cleaning products. Although the chemical was not reported to be used in cosmetics in the 2006 High Volume Industrial Chemical survey, the chemical was reported for this use in the 2002 High Volume Industrial Chemical survey. International reports also suggest that the chemical may be present in cosmetics as a contaminant of fatty acid-diethanolamide surfactants (IARC, 2012).

The chemical is currently listed on Schedule 6 of the SUSMP for preparations containing > 20% of the chemical and in Schedule 5 for preparations containing > 5% and $\leq$ 20% of the chemical. A number of warning statements, first aid instructions and safety directions apply for scheduled chemicals.

While the chemical is currently controlled through scheduling, there is some concern for potential carcinogenicity and reproductive/developmental toxicity. This requires substantiation through conducting a Tier III assessment.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may 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 local and systemic (acute and long-term) health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise 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

The chemical is recommended for Tier III assessment to examine whether the chemical should be classified for carcinogenicity and reproductive/developmental toxicity. The Tier III assessment may also consider whether further regulatory controls are required for public health.

All other risks are considered to have been sufficiently assessed at the Tier II level, subject to implementing any risk management recommendations, and provided that all 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 if swallowed (Xn; R22)*	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)
Repeat Dose Toxicity	Harmful: danger of serious damage to health by prolonged exposure in contact with skin (Xn; R48/21) Harmful: Danger of serious damage to health by prolonged exposure if swallowed (Xn; R48/22)*	May cause damage to organs through prolonged or repeated exposure through the dermal route - Cat. 2 (H373) May cause damage to organs through prolonged or repeated exposure through the oral route - Cat. 2 (H373)

[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 consumers

Products containing the chemical should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from oral, 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 closed systems or isolating operations;
- 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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Last update 12 September 2013

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