Ethanol, 2-amino-: Human health tier II assessment

12 September 2013

CAS Number: 141-43-5

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	2-aminoethanol monoethanolamine (MEA) ethanolamine 2-hydroxyethanamine glycinol
Structural Formula	
Molecular Formula	C2H7NO
Molecular Weight (g/mol)	61.08
Appearance and Odour (where available)	Colourless, viscous liquid or solid with fishy/ammoniacal odour.
SMILES	C(O)CN

Import, Manufacture and Use

Australian

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported introduction 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 corrosion inhibitor; and
- in surface active agents.

The chemical has reported commercial use including in:

- absorbents and adsorbents;
- explosive materials; and
- softeners.

The chemical has reported site-limited use including in:

- engineering; and
- manufacturing other chemicals.

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program—OECD HPV, the US Environmental Protection Agency's Aggregated Computer Toxicology Resource—ACToR, and the US National Library of Medicine's Hazardous Substances Data Bank—HSDB.

The chemical has reported cosmetic use:

- as a pH adjuster and buffering agent in hair waving solutions;
- in after shave lotion;
- in shampoos and soaps; and
- in hair colour sprays (aerosol).

The chemical has reported domestic use including:

- in polishes;
- as a surfactant/emulsifier;
- in adhesives and binding agents;
- in detergents and cleaning/washing products; and

- in textile softeners.

The chemical has reported commercial use including:

- in the synthesis of surface active agents (dyestuffs);
- in polyurethane foams;
- as a corrosion inhibitor;
- in nonionic detergents used in dry cleaning and wool treatment;
- in lubricants in the textile industry;
- in cement additives;
- as a remover/scrubber of CO_2 (carbon dioxide) and H_2S (hydrogen sulfide) from natural gas and other gases; and
- in plasticisers.

The chemical has reported site-limited use including in manufacturing other chemicals such as ammonia and antibiotics.

Restrictions

Australian

This chemical is listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in schedules 4, 5 and 6.

'Schedule 4 chemicals are labelled with Prescription Only Medicine, or Prescription Animal Remedy. These are substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription':

"ETHANOLAMINE in preparations for injection."

'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':

"ETHANOLAMINE (excluding its salts and derivatives) in preparations containing 20 per cent or less of ethanolamine except:

(a) when included in Schedule 4; or

(b) in preparations containing 5 per cent or less of ethanolamine."

'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':

"ETHANOLAMINE (excluding its salts and derivatives) except:

(a) when included in Schedule 4 or 5; or

(b) in preparations containing 5 per cent or less of ethanolamine."

International

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

European Union (EU) Inventory of Ingredients used in Cosmetic Products: The chemical used as buffering agent with restriction III/1-61: Maximum secondary amine content is 0.5 %. The following restrictions also apply:

- do not use with nitrosating systems;
- minimum purity: 99 %;
- maximum secondary amine content: 0.5 % (applies to raw materials);
- maximum nitrosamine content: 50 microgram/kg; and
- keep in nitrite-free containers.

European Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food—Annex I—The chemical is used as an additive or polymer production aid at the chemical Specific Migration Limit (SML) of 0.05 mg/kg for indirect food contact only, behind a PET layer, but not to be used for articles in contact with fatty foods for which simulant D (olive oil) is laid down.

US Cosmetic Ingredient Review (CIR): Cosmetic ingredients found safe, with qualifications—'The chemical is safe for use in rinse-off products, but should not be used in leave-on products'.

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; R20/21/22 (acute toxicity)

C; R34 (corrosive)

Exposure Standards

Australian

The chemical has an exposure standard of 7.5 mg/m³ (3 ppm) time weighted average (TWA) and 15 mg/m³ (6 ppm) short-term exposure limit (STEL).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 2.5–8 mg/m³ in countries such as Canada, Denmark, Ireland, France, Germany, Japan, Norway, Sweden, Spain, Switzerland, United Kingdom, and the USA.

An exposure limit (STEL) of 7.6–15 mg/m³ in countries such as Canada, Ireland, France, Sweden, Switzerland, United Kingdom, and the USA.

Health Hazard Information

Toxicokinetics

The chemical occurs naturally in a group of phospholipids in mammals, known as phosphatides.

Although the chemical is readily metabolised in the skin, tissues and other organs and excreted in the urine, the liver is the most active site of metabolism for the chemical, containing 24 % of the applied radioactive dose in mice. The other organs such as kidneys, lungs, brain, and the heart contain only 2.53, 0.55, 0.27, and 0.15 % of the applied radioactive dose, respectively. It has been suggested that, based on an in vitro dermal absorption study, the potential for dermal absorption of the chemical would be less for humans than it would be for rats, rabbits, and mice. The total absorbed dose of the chemical may be higher for a diluted solution of the chemical in water compared with the undiluted solution. In mammals, the alcohol group of the chemical is phosphorylated. Phosphorylated ethanolamine is transformed to cytidine monophosphate to form cytidine-5'-di-phosphoethanolamine and phospholipids via diacylglycerol (CIR, 2012; HSDB, REACH).

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 (median lethal dose—LD50—1089 mg/kg bw in rats) support this classification (REACH).

Dermal

The chemical is classified as hazardous with the risk phrase ‘Harmful in contact with skin’ (Xn; R21) in HSIS (Safe Work Australia). The available data (median lethal dose—LD50—1025 mg/kg bw in rabbits) support this classification (IUCLID, 2000; HSDB).

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Harmful by inhalation’ (Xn; R20) in HSIS (Safe Work Australia). While the available data do not support this classification, in the absence of more comprehensive information, there is insufficient evidence to support a recommendation to amend this classification.

Corrosion / Irritation

Corrosivity

The chemical is classified as hazardous with the risk phrase ‘Causes burns’ (C; R34) in HSIS (Safe Work Australia). The available data support this classification (IUCLID, 2000; CIR, 2012; REACH).

The chemical was reported to be corrosive to rabbit skin at varied concentrations (20–100 %). While a concentration of ≥10 % was also corrosive when applied to the ears and shaved skin of the abdomen in rabbits, a lower concentration of >1 % was only extremely irritating. The chemical was still irritating at a lower concentration of 1 % (CIR, 2012; REACH).

Sensitisation

Skin Sensitisation

The chemical was not sensitising to the skin of guinea pigs.

In a maximisation study, groups of 15 Dunkin Hartley guinea pigs were tested using intradermal induction at 0.6 % and topical induction at 10.3 % of the chemical, following pretreatment with 10 % sodium dodecyl sulphate. At challenge with 0.41 %, 2.05 % and 4.1 % of the chemical, 3/15, 2/15 and 3/15 animals (respectively) reacted positively after 72 hours and 2/15 animals showed a reaction to the vehicle (water). The test was repeated using the same protocol and the results were 0/15, 2/15 and 1/15 animals reacting to the chemical, respectively. In both tests, the 12 control animals did not react to the chemical or the vehicle (CIR, 2012).

In a local lymph node assay (LLNA), groups of six female CBA/Ca mice were treated with a salt of the chemical (ethanolamine HCl) at 10, 40 and 70 % concentrations. The salt was not a skin sensitiser (CIR, 2012).

Observation in humans

The chemical was not a sensitiser in clinical studies on humans when formulations containing up to 5.9 % concentrations of the chemical were tested in a 48-hour occlusive patch test or in repeated insult semi-occlusive patches (CIR, 2012).

Several patch tests were also performed on groups of metal workers with dermatitis, using 2 % of the chemical in petroleum jelly for one or two days. In the two studies, positive reactions were reported on day three in 3/155 patients (1.9 %) and in 40/199 patients (11.6 %). In another study, patients with suspected dermatitis to metal-working fluids containing the chemical showed higher positive reaction rate (12.2 %) compared with the control group (1.3 %) (CIR, 2012).

Human inhalation exposure to the chemical was reported to cause allergic symptoms such as dyspnoea and asthma as well as acute liver damage and chronic hepatitis. No details on the amount or duration of exposure were reported (CIR, 2012).

Repeated Dose Toxicity

Oral

Considering the lowest observed-effect level (LOEL) available from a 90-day rat study (640 mg/kg bw/day), and based on the treatment-related effects reported in this repeated dose toxicity study, the chemical is not considered to cause serious damage to health from repeated oral exposure.

In a 90-day repeated dose toxicity study, groups of 10 rats were fed the chemical at up to 2670 mg/kg bw/day. The reported no observed adverse level (NOAEL) was 320 mg/kg bw/day, based on increased liver and kidney weights at ≥640 mg/kg bw/day. Deaths and histopathological changes were reported at doses ≥1250 mg/kg bw/day (IUCLID, 2000; CIR, 2012).

In a two-year repeated dose toxicity study, groups of 12 beagle dogs were fed up to 97.5 mg/kg bw/day of a hair dye product that contained 22.4 % of the chemical (actual dose 22 mg/kg bw/day). As no toxic effects were observed, a NOAEL of 22 mg/kg bw/day was determined for this study (IUCLID, 2000; CIR, 2012).

In a two generation dietary study (see **Reproductive and develomental toxicity**), Wistar rats were administered the chemical (as ethanolamine HCl) at doses of 100, 300, and 1000 mg/kg bw/day for 75 days before mating. Although the chemical produced no clinical adverse effects on F0 and F1 parental animals at low (100 mg/kg bw/day) and mid doses (300 mg/kg bw/day), reduced food consumption and/or body weight gain were noted in the high dose F0 females. As decreased absolute weights of cauda epididymis and epididymides were also considered to be treatment related in males of 1000 mg/kg bw/day group, a NOAEL of 300 mg/kg bw/day was established for fertility, reproductive performance and systemic toxicity in parental F0 and F1 rats (CIR, 2012; REACH).

Dermal

No data are available.

Inhalation

Based on the available information, the chemical is not likely to cause serious damage to health from repeated inhalation exposure.

In a 28-day inhalation toxicity study, Wistar rats were exposed (nose only) to the chemical at levels of 10, 50, and 150 mg/m³. A no observed adverse effect concentration (NOAEC) of 10 mg/m³ was determined for local effects, based on concentration-related lesions in the larynx, trachea and lung. As adverse systemic effects were not noted at the highest tested concentration, a systemic NOAEC of 150 mg/m³ was established (REACH).

In another inhalation toxicity study, animals (rats, mice, and rabbits) were exposed to the chemical at 26 mg/L daily for five weeks. Respiratory tract irritation and non-specific mild degenerative changes of the liver and kidneys were observed. Behavioural effects in dogs (progressive stages of excitation followed by depression) were noted following repeated inhalation of the chemical at low doses (0.029 mg/L) (HSDB).

In a 6-month inhalation toxicity study, a group of rats was exposed to 200–400 mg/m³ (80–160 ppm) of the chemical as vapour for five hours/day. Reduced body weight, changes in haematological parameters, diuresis, increased protein in urine and reduced synthesis of hippuric acid were reported (IUCLID, 2000). In another toxicity study, dogs and rodents exposed to the chemical as vapour at 160–250 mg/m³ (66–102 ppm) for 30 days showed behavioural and haematological changes, pulmonary and hepatic inflammation, and hepatic and renal damage. Following exposure to 29–64 mg/m³ (12–26 ppm) of the chemical as vapour for 90 days, both dogs and rodents showed skin irritation and lethargy with no mortality (CIR, 2012). In a 40–60 day repeated toxicity study, dogs, guinea pigs and rats exposed to 12.5–15 mg/m³ (5–6 ppm) of the chemical as vapour, showed skin irritation and lethargy (IUCLID, 2000).

Genotoxicity

Based on the data available, the chemical is unlikely to be a genotoxic.

The chemical was reported to be negative in Ames tests at up to 4000 µg/plate concentrations (*Salmonella typhimurium* TA98, TA100, TA1535, and TA1537), in the presence and absence of metabolic activation. The chemical also tested negative in cytogenetic assays in rat hepatocytes (RL4) at up to 400 µg/mL, but slight positive results were recorded in human lymphocytes at concentrations of 0.61–61.08 µg/mL, both without metabolic activation. The chemical also gave negative results in a mitotic recombination assay (*Saccharomyces cerevisiae*) at up to 5000 µg/mL, in a cell transformation test (hamster embryo cells) at up to 500 µg/mL (with and without metabolic activation), and in a sister chromatid exchange assay (human lymphocytes) at up to 61.08 µg/plate concentrations. The chemical also tested negative in Naval Medical Research Institute (NMRI) mice in an vivo micronucleus test up to a concentration of 1500 mg/kg bw (IUCLID, 2000; REACH).

Carcinogenicity

While no reliable data are available, the chemical is not anticipated to be a carcinogen. The chemical was negative for genotoxicity and an analogue (similar chemical), triethanolamine is not classifiable as carcinogenic to humans (Group 3) (IARC, 2000). Diethanolamine, which is evaluated as possibly carcinogenic to humans (Group 2B) (IARC, 2012), is not an appropriate analogue to assess this chemical due to its high hepatotoxicity (NICNAS, 2013).

The Cosmetic Ingredient Review Expert Panel reported that the chemical should not be used in cosmetic products containing N-nitrosating agents to prevent the formation of possibly carcinogenic nitrosamines (CIR, 2012).

Reproductive and Developmental Toxicity

Based on the information available, the chemical is considered to be not reproductive or developmentally toxic.

In a two-generation dietary study, Wistar rats were administered the chemical salt at doses of 100, 300, and 1000 mg/kg bw/day for 75 days before mating. There were no test-substance-related adverse fertility or reproductive performance effects in the F0 or F1 animals up to a dose of 300 mg/kg bw/day. Decreased absolute weights of cauda epididymis and epididymides were

considered to be treatment-related in males in the 1000 mg/kg bw/day group. A NOAEL of 300 mg/kg bw/day was established for fertility, reproductive performance, and systemic toxicity in parental F0 and F1 rats. There was no indication of any developmental toxicity in the F1 and F2 pups up to a dose level of 1000 mg/kg bw/day. A NOAEL of 1000 mg/kg bw/day for pre- and postnatal developmental toxicity was established (CIR, 2012; REACH).

In a reproductive and developmental toxicity study, a group of 40 pregnant Wistar rats was orally dosed with the chemical at up to 450 mg/kg bw/day on days 6–15 of gestation. The NOAEL for maternal toxicity was determined to be 120 mg/kg bw, based on the statistically significant decreases in feed consumption, maternal body weights, and body weight gains at the highest dose (450 mg/kg bw/day). There was no evidence of any treatment-related effects on reproductive parameters, skeletal malformations, postnatal growth or on the viability of offspring. It was concluded that the chemical was not developmentally toxic following repeated oral exposure at up to 450 mg/kg bw/day (IUCLID, 2000; HSDB; CIR, 2012; REACH).

In another study, pregnant Sprague Dawley (SD) rats and New Zealand White rabbits were dermally treated (six hours/daily) with the chemical up to 225 mg/kg bw/day on gestational days 6–15 in rats and up to 75 mg/kg bw/day on gestational days 6–18 in rabbits. A maternal NOAEL of 75 mg/kg bw/day was established for rats, based on decreased body weight gain and skin irritation at 225 mg/kg bw/day. In rabbits, a maternal NOAEL of 10 mg/kg bw/day was established, based on local skin irritation effects at the next higher doses of 25 and 75 mg/kg bw/day. A developmental NOAEL of 225 and 75 mg/kg bw/day was also determined for rats and rabbits, respectively, based on lack of developmental effects at the highest tested doses. It was concluded that the chemical is not developmentally toxic following repeated dermal exposure at up 225 mg/kg bw/day in rats and up to 75 mg/kg bw/day in rabbits (IUCLID, 2000; CIR, 2012; HSDB; REACH).

In a developmental toxicity study, groups of pregnant rats were administered the chemical by gavage at doses of 50, 150, 300 or 500 mg/kg bw/day on days 6–15 of gestation. Animals showed no clinical signs of toxicity and there were no mortalities. A maternal toxicity NOAEL of 300 mg/kg bw/day was established in this study, based on effects on food consumption (decreased), body weight gain (decreased), and clinical chemistry (reduced total protein and albumin values) at the next higher dose of 500 mg/kg bw/day. A teratogenicity NOAEL of 500 mg/kg bw/day was also determined, based on the absence of treatment-related developmental effects at the highest tested dose (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include local effects (corrosivity). It is also acutely harmful by all routes of exposure.

Public Risk Characterisation

Although use in cosmetic products in Australia is not known, the chemical is reported to be used in cosmetic products overseas, as a buffering agent in hair waving solutions, after shave lotion, shampoos, soaps and hair colour sprays (aerosol). When used as a buffering agent, the chemical is largely present in the form of non corrosive salts. Therefore, public exposure to high concentrations of the chemical is not expected through cosmetic uses. If the concentrations in cosmetics are low, corrosive effects are not expected and, therefore, the risk to public health is not considered to be unreasonable. Further risk management is not considered necessary for public safety.

It is also noted that the chemical and its salt (ethanolamine HCl) were also stated to be safe for use in rinse off products only up to a concentration of 18 %, when formulated to be non-irritating. It was also concluded that, if there is a possibility of formation of N-nitroso compounds, the chemical should not be used in these cosmetic products (CIR, 2012).

Although the concentration of the chemical in domestic products is not known, the general public may be exposed to the chemical through dermal and/or inhalation routes when using domestic products containing the chemical. The chemical is currently listed in the Schedule 4, Schedule 5, and Schedule 6 of the SUSMP. At concentrations greater than 5 %, a number of warning statements, safety directions, and first aid instructions apply to any domestic products containing this chemical. The current controls are considered adequate to minimise the risk to public health posed by any domestic use of this chemical. Therefore, the risk to public health is not considered to be unreasonable.

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 equipment cleaning and maintenance. 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 acute and local health effects, the chemical may 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.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Public Health

At present, the chemical falls within the scope of the listing of in Schedules 4,5 and 6 of the SUSMP for preparations containing 5 % or less concentrations.

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 in contact with skin (Xn; R21)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312) Harmful if inhaled - Cat. 4 (H332)
Irritation / Corrosivity	Causes burns (C; R34)*	Causes severe skin burns and eye damage - Cat. 1 (H314)

[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.

References

Cosmetic Ingredient Review (CIR) 2012. Review Expert Panel. Final amended report on the safety assessment of ethanolamine and ethanolamine salts as used in cosmetics. Accessed July 2013 at http://www.cir-safety.org/ingredients/glossary/E.

Cosmetics Directive (CosIng). Ethanolamine (141-43-5). Accessed July 2013 at http://ec.europa.eu/consumers/cosmetics/cosing/

Galleria Chemica. Accessed July 2013 at http://jr.chemwatch.net/galleria/

Hazardous Substances Data Bank (HSDB). US National Library of Medicine. Accessed July 2013 at http://toxnet.nlm.nih.gov.

International Agency for Reseach on Cancer (IARC) 2000. IARC monographs on the evaluation of carcinogenic risks to humans. Diethanolamine (111-42-2). Volume 77 (some industrial chemicals). Accessed July 2013 at http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-14.pdf

International Agency for Reseach on Cancer (IARC) 2012. IARC monographs on the evaluation of carcinogenic risks to humans. Diethanolamine (111-42-2). Volume 101 (some industrial chemicals). Accessed September 2013 at http://monographs.iarc.fr/ENG/Monographs/vol101/index.php

International Uniform Chemical Information Database (IUCLID) 2000. Dataset. 2-aminoethanol (141-43-5). Accessed July 2013 at http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/141435.pdf

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 2013. Inventory Multi-tiered Assessment and Prioritisation (IMAP) Human Health Tier II Assessment for diethanolamine (ethanol, 2,2'-iminobis-) (CAS No. 111-42-2). Available at http://www.nicnas.gov.au

NICNAS 2006. Australian High Volume Industrial Chemicals List (AHVICL). Accessed July 2013 at http://www.nicnas.gov.au/Industry/Australian_High_Volume_Industrial_Chemicals/NICNAS_AHVICL_2006_PDF.pdf

Personal Care Product Council (INCI Dictionary). Accessed July 2013 at http://www.ctfa gov.org/jsp/gov/GovHomePage.jsp

REACH Dossier. 2-aminoethanol (141-43-5). Accessed July 2013 at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Safe Work Australia Hazardous Substances Information System (HSIS). Accessed July 2013 at http://hsis.safeworkaustralia.gov.au/HazardousSubstance

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) 2012. Australian Government. Department of Health and Ageing. Therapeutic Goods Administration, (the SUSMP 3) No. 3, 2012. Accessed May 2013 at http://www.comlaw.gov.au/Details/F2012L01200

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