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

22 November 2013

CAS Number: 102-71-6

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.

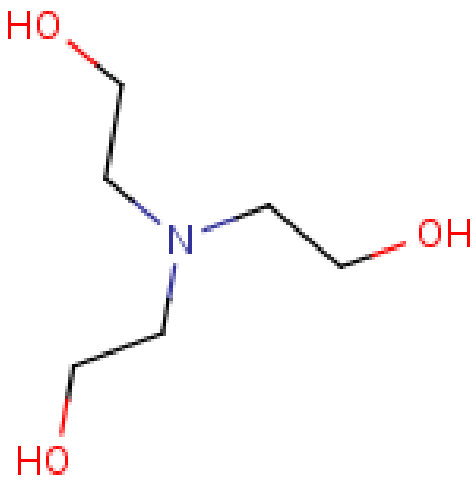
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Triethanolamine (TEA) 2,2,2-Trihydroxyethylamine 2,2,2-Nitrilotriethanol Tris(2-hydroxyethyl)amine Nitrilotriethanol
Structural Formula	
Molecular Formula	C6H15NO3
Molecular Weight (g/mol)	149.19
Appearance and Odour (where available)	Pale yellow to colourless viscous liquid with a slight ammoniacal odour.
SMILES	C(O)CN(CCO)CCO

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 uses were reported under previous mandatory and/or voluntary calls for information:

The chemical has reported cosmetic use as a:

- pH control and neutralising agent;
- tattoo removal cream applied intradermally.

The chemical has reported domestic use including:

- as a neutralising and emulsifying agent in laundry detergents and household cleaning products.

The chemical has reported commercial use including:

- in solvents and construction material (cement) additives;
- as a corrosion inhibitor; and
- in paints and printing inks (as a pigment dispersion agent and pH control).

The chemical has reported site-limited use including:

- in manufacturing other chemicals;
- in explosive manufacture; and
- in waste oil treatment.

International

The following international uses have been identified through Galleria Chemica; the European Commission Cosmetic Ingredients and Substances (CosIng) 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 is used in various cosmetics (hair removal gels and creams, general hand cream, anti-dandruff shampoo, mascara) for its buffering, emulsifying, masking and surfactant properties.

The chemical has reported domestic use including in:

- detergents (laundry powders);
- cleaning and polishing products (bathroom cleaners, leather and car waxes); and
- disinfectants (in aerosol disinfectant air fresheners).

The chemical has reported commercial use including in:

- lubricants;
- corrosion inhibitors; and

- paints.

The chemical has reported site-limited use including:

- extracting hydrogen sulphide gas;
- producing other chemicals (piperazine); and
- as a chelating agent.

Restrictions

Australian

This chemical (excluding its salts and derivatives, except in preparations containing 5 % or less of triethanolamine) is listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in Schedule 5.

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.

International

International restrictions include:

European Union (EU) cosmetic restriction III/62: Authorised use in leave-on products at a maximum concentration of 2.5 % in the finished product. Furthermore, for both leave-on and rinse-off products the following restrictions 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.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not classified on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

The chemical has an exposure standard of 5 mg/m³ time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 3.1–5 mg/m³ in different countries such as USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

Toxicokinetics

In a study in Fischer 344 (F344) rats, 53–63 % of an oral dose was absorbed from the digestive tract of the animals within 30 to 60 minutes. In dermal studies, 70 % of ^{14}C- labelled triethanolamine applied to the skin of $B6C3F_1$ mice and F344 rats (1000–2000 mg/kg bw) with or without occlusion, was absorbed within 24–48 hours by the skin. Oral administration of the chemical to male and female rats as a single dose, or as repeated doses for 5-6 days (dosing details not specified) resulted in similar metabolism. Twenty-four hours after administration of the single dose, unmetabolised triethanolamine was detected in the urine and faeces (53 % and 20 %, respectively). With repeated administration, the excretion rate (each day) remained constant. A metabolite, triethanolamine glucuronide, was detected, but in small amounts (not specified), suggesting that triethanolamine is excreted mostly unmetabolised. In a further study in mice and rats given either intravenous injections (1 mg/kg bw) or dermal applications (1000–2000 mg/kg bw) of triethanolamine, 50–70 % of the dose was excreted in urine and 10–30 % in faeces. The half-life of the chemical intravenously injected (1 mg/kg bw) or dermally applied (2000 mg/kg bw) was 10 hours and 31 hours, respectively (NTP, 1999; CIR, 2011).

Acute Toxicity

Oral

The chemical was of low acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in experimental animals (rats, mice and guinea pigs) is 5200–11300 mg/kg bw. Observed sub-lethal effects included agitation, elevated respiration and reduced grooming (NIWL, 2003; CIR, 2011).

Dermal

The chemical was of low acute toxicity in animal tests following dermal exposure. The median lethal dose (LD50) in rabbits is greater than 2000 mg/kg bw. Observed sublethal effects included mild erythema 24 hours after exposure, resolving after 6–10 days (REACH; CIR, 2011).

Inhalation

Due to the low vapour pressure of the chemical, the highest attainable vapour concentration is 1.8 mg/m³. In a study conducted in rats (strain not specified) exposed to the chemical (1.8 mg/m³), no deaths were reported. One out of 12 rats exposed showed signs of chronic bronchitis (REACH).

Corrosion / Irritation

Respiratory Irritation

Based on the available information a classification for respiratory irritation is warranted (refer to **Repeat dose toxicity—inhalation**).

Skin Irritation

Based on the available data, the chemical is considered a skin irritant (based on observations in humans), and warrants classification.

The chemical was not irritating to skin in studies that were performed in accordance with OECD Test Guideline (TG) 404 (REACH). In one study, three Vienna White Rabbits were dermally exposed to the chemical (85 % concentration of triethanolamine and 15 % diethanolamine) through a occlusive patch for four hours. Neither oedema nor erythema was observed throughout the observation period (REACH).

In animal studies with repeated exposures, the chemical was applied to rabbit ears over 10 open applications, with 10 unoccluded applications to abdominal intact skin, or with three semi-occluded 24-hour applications to abraded skin. These exposures resulted in slight to moderate irritation (CIR, 2013).

In a two-year repeated dose dermal study, the chemical caused lesions consisting of acanthosis (thickened skin), ulceration and chronic active inflammation at the application site (refer to **Repeated dose toxicity**).

Eye Irritation

The chemical is an eye irritant. While the available data do not meet classification criteria under the Approved Criteria for Classifying Hazardous Substances (NOHSC), the data meet classification criteria under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

In two studies conducted similarly to OECD TG 405 the average Draize scores for corneal opacity, redness of the conjunctivae and chemosis were 1, 2 and 1.75 respectively (REACH). In one study, the corneal opacity in one animal had not fully resolved by day eight of the observation period. However, based on the results seen in the other animals, it is expected that the corneal opacity would fully resolve had the observation period continued for 21 days.

Observation in humans

The CIR (2013) reported that, in clinical provocative tests using 5–10 ‘hyperreactors,’ 100 % triethanolamine produced an irritant reaction on non-scarified skin, 10 % triethanolamine was a marked irritant on scarified skin and 5 % triethanolamine in ethanol was slightly irritating to scarified skin (CIR, 2013).

In studies testing formulations containing 0.45–2.4 % of the chemical, no irritation was observed (CIR, 2013). According to the CIR expert panel, formulations containing 0.83–20.04 % triethanolamine were irritating. However, given the absence of detailed information regarding the formulations, this opinion is difficult to interpret.

Sensitisation

Skin Sensitisation

The chemical is not a skin sensitiser.

The negative results observed for the chemical in several guinea pig maximisation tests and one local lymph node assay support a conclusion that the chemical is not a skin sensitiser (REACH; CIR, 2013).

Repeated Dose Toxicity

Oral

In the only available well reported study, the no observed adverse effect level (NOAEL) was > 1000 mg/kg bw/day. Based on the available data, the chemical does not meet the criteria for classification for repeated dose toxicity through the oral route.

The NOAEL available from a 90 day rat (COX CD) study was > 1000 mg/kg bw/day. The study was conducted similarly to OECD TG 408. No animal mortality or histopathological changes were observed and the only effects reported were non-significant increases in liver and kidney organ weights (REACH).

In another study, F344 rats and $B6C3F_1$ mice were exposed to drinking water containing 2 - 8 % of the chemical for 14 days. Rats and mice exposed to ≥ 4 % of the chemical had decreased body weights and one animal in the high dose group was euthanised due to severe dehydration (CIR, 2013).

In a further study, rats (species not specified) and guinea pigs were orally dosed with the chemical (200 - 2610 mg/kg bw/day and 200 - 1600 mg/kg bw/day, respectively) for 60 - 180 days. It was reported that there was evidence of hepatic and renal damage in both species. However, the nature of the damage or dose at which the effects were found were not reported. Mortality was observed in some rats administered 300 mg/kg bw/day or greater (CIR, 2011). It was not reported whether the mortality was treatment related.

Dermal

The chemical is reported to cause local (acanthosis, inflammation and ulceration of the skin) and systemic (increased kidney weights and nephropathy in female rats) effects following repeated dermal exposure. The NOAEL for systemic renal effects was 250 mg/kg bw/day in female rats only (NTP, 1999). The systemic effects were observed at concentrations that do not warrant a hazard classification.

13 week studies:

In a 13-week study, 1 mg/kg bw of a hair dye formulation containing 0.1 % to 1.5 % of the chemical was applied to the backs of 12 rabbits for one hour, twice weekly. The test site skin was abraded for half of the animals. In the doses used in this study, there was no evidence of systemic toxicity or histomorphologic changes (CIR, 2013).

In a 13 week study performed by the NTP, 250 - 2000 mg/kg bw/day dermally applied to $B6C3F_1$ mice showed local irritation and inflammation at the highest dose (NTP, 1999). Microscopically, acanthosis (thickening of the skin) was evident across all dose groups, with increasing severity in a dose dependent manner. In the same study, F344 rats dermally exposed to 0, 125, 250, 500 or 1000 mg/kg bw/day of the chemical had increased kidney weights in animals administered 500 mg/kg bw/day. Histopathological changes included local effects (acanthosis and inflammation at treatment site) and systemic effects (nephropathy in female rats and hypertrophy of the pituitary gland pars intermedia in both sexes). The NOAEL for systemic toxicity was derived to be 250 mg/kg bw/day.

2 year studies:

In a two year repeated dose study, male and female rats (F344/N) topically administered triethanolamine (0, 32, 63 or 125 mg/kg bw/day (males); 0, 63, 125 or 250 mg/kg bw/day (females)) developed lesions including acanthosis, ulceration and chronic active inflammation at the application site. Acanthosis and inflammation were observed at all treatment dose levels in both sexes. At the interim 15 month evaluation period, females administered 250 mg/kg bw/day chemical had significantly higher left and right kidney weights when compared with controls. However, there appeared to be no dose response relationship in the histopathological findings (renal tubule adenomas and hyperplasia) for renal effects in both males and females. Mortality was reported to be slightly reduced in female rats receiving the highest dose.

A similar study was also carried out in B6C3F1 mice in males (0, 200, 630 or 2000 mg/kg bw/day) and females (0, 100, 300 or 1000 mg/kg bw/day). Similar to the study conducted in rats, acanthosis, crust formation and inflammation of the skin were observed in mice topically administered triethanolamine (NTP, 1999) for two years. In mice, hepatic rather than renal effects were reported (hepatocellular adenomas, hepatoblastomas and hepatocarcinoma), particularly at the highest dose administered (refer to **Carcinogenicity** section).

Inhalation

Based on the available information, no hazard classification for repeated dose inhalation toxicity is recommended. However, a classification for respiratory irritation is warranted.

In a 28 day repeated dose inhalation toxicity study in male and female Wistar rats, the lowest observed effect concentration (LOEC) for the chemical is estimated to be 0.02 mg/L (in male rats only). Histopathological investigations indicated the chemical (0.02 and 0.5 mg/L in males and females, respectively) caused irritation of the upper respiratory tract (larynx) as indicated through inflammatory changes in the mucosal lining of the larynx (REACH).

Genotoxicity

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

In vitro, 33 to 3333 μg/plate of the chemical did not induce mutations in several *Salmonella typhimurium* strains with or without metabolic activation (NTP, 1999). Similarly, the chemical was not genotoxic to *Escherichia coli* with or without metabolic activation (NTP, 1999). Furthermore, the chemical was not genotoxic in a sister chromatid exchange (SCE) study using Chinese hamster ovary (CHO) cells (NTP, 1999). Significant SCEs were only observed at cytotoxic doses (2520 μg/mL) (NTP, 1999).

In vivo, the results of a peripheral blood micronucleus test were negative. There were no reported increases in micronucleated cells (polychromatic erythrocytes (PCE) or normochromatic erythrocytes (NCE)) (NTP, 1999).

Carcinogenicity

Considering the animal studies conducted, there is no evidence of carcinogenicity through the oral route and equivocal evidence of carcinogenicity through the dermal route. The available data do not warrant hazard classification.

The International Agency for Research on Cancer (IARC) has classified the chemical as 'not classifiable as to its carcinogenicity to humans' (Group 3), based on inadequate evidence for carcinogenicity in humans and experimental animals (IARC, 2000).

Oral administration of the chemical (0 – 2 %) in food to 50 male and female mice ($B6C3F_1$) for 82 weeks did not show any significant increase in treatment related tumour incidence. A similar study conducted in F344 rats resulted in increased body weight loss and mortality at week 60 in females treated with the highest dose (2 % of the chemical). Due to increased mortality, the dose was halved at week 68. A dose dependent increase in mortality was noted in females due to nephrotoxicity at the end of the study. As in the mouse study, no treatment related increase in the incidence of tumours was noted (IARC, 2000).

A study using genetically modified mice (female Tg.Ac) was conducted to evaluate the carcinogenic activity of the chemical. This genetic modification sensitises the animal to carcinogenic agents and hence is able to distinguish between chemical related and sporadic tumours (Spalding et al, 2000). The chemical (3 - 30 mg) was applied in the form of a skin paint for 10 weeks. There was no sign of chronic irritation or ulceration during the exposure period and, compared with positive controls, there was no increase in the incidence of skin tumours in mice treated with the chemical (IARC, 2000).

In the most recent National Toxicology Program (NTP) study (not reviewed by IARC (2000), mice ($B6C3F_1$) were treated 5 days per week dermally (males: 0, 200, 630 or 2000 mg/kg bw/day; females: 0, 100, 300 or 1000 mg/kg bw/day chemical) for 104-105 weeks (NTP, 2004). The NTP concluded that there was equivocal evidence of carcinogenicity in male mice based on occurrence of liver haemangiosarcomas without a dose-response relationship. The NTP also concluded that there is some evidence of carcinogenic activity in female mice based on increased incidence of hepatocellular adenomas. There was no dose-response relationship in the number of hepatocellular carcinomas.

The available data are equivocal considering that hepatocellular adenomas were only seen in female mice through the dermal route and no significant increase in treatment related tumour incidence was observed in either rat or mice studies through the oral route. The Cosmetic Ingredient Review Expert Panel concluded that the chemical may cause liver tumours in mice through a choline-depletion mode of action that is not relevant to humans (CIR, 2013). In a study where female mice ($B6C3F_1$) were

dosed dermally with 10 – 1000 mg/kg bw/day chemical, five days/week for three weeks, levels of phosphocholine and betaine levels were decreased. The expert panel reported that humans are far less sensitive to this deficiency (CIR, 2013).

The Cosmetic Ingredient Review Expert Panel reported that while the chemical does not directly react with N-nitrosating agents to form nitrosamines, the chemical could undergo hydrolytic cleavage that results in diethanolamine. This in turn can be N-nitrosated to chemicals that may be carcinogenic. Therefore, the chemical should not be used in consumer products where N-nitroso compounds could be formed (CIR, 2013).

Reproductive and Developmental Toxicity

The chemical does not show specific reproductive or developmental toxicity through the dermal route and is equivocal through the oral route. The available data do not warrant a hazard classification.

In a recent study carried out similarly to OECD TG 421 (Reproduction/Developmental Toxicity Screening Test), male and female Wistar rats were exposed to the chemical (100, 300 or 1000 mg/kg bw/day) via oral gavage during a two week pre-mating period, a mating period up to a maximum of two weeks, approximately one week post-mating in males, and the entire gestation period as well as four days of lactation in females. Most animals dosed at 1000 mg/kg bw/day and one animal dosed at 100 mg/kg bw/day showed transient salivation for a few minutes immediately after each treatment. This was likely to be induced by the unpleasant taste of the test substance or by local irritation of the upper digestive tract and is not considered to be a sign of systemic toxicity (REACH). The slightly lower body weight gain in females dosed with 1000 mg/kg bw/day of the chemical during gestation was likely caused by the increased post implantation loss rather than a systemic toxic effect of the test compound (REACH). No effects were noted with respect to male reproduction. In pregnant rats, lower mean number of implantations (20 % below control), increased post implantation loss (19.4 % compared with 3.7 % in control) and a lower average litter size (33 % below control) was reported at the highest dose (1000 mg/kg bw/day) (REACH). There were no reported developmental effects noted in the offspring. While this study suggests a potential concern for reproductive/developmental toxicity at high doses (i.e. at the limit dose) there is a concern whether the observed reproductive/developmental effects were due to maternal systemic alkalosis considering that the test substance does not appear to be buffered prior to oral administration.

Dermal application of 500 mg/kg bw/day of the chemical for 10 weeks prior to mating, during mating, gestation and lactation had no effect on mating, fertility or offspring developmental effects (NTP, 1999). In a similar study conducted in mice (Swiss CD-1) with the chemical administered up to 2000 mg/kg bw/day no chemical related effects were observed other than irritation at the site of application and ruffled fur in females (NTP, 1999).

In a developmental study in mice the chemical was administered by gavage on gestation days 6 - 15 at 1125 mg/kg bw/day. The chemical had no effect on "maternal mortality, the number of viable litters, litter size, or survival and body weight of the pups" (NTP, 1999).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include respiratory, skin and eye irritation.

As a tertiary amine, under certain conditions, the chemical may indirectly give rise to the formation of nitrosamines that are potent carcinogens (CIR,2013; SCCS, 2012). However, the potential for nitrosamine formation is significantly less when compared with secondary amines such as diethanolamine (DEA).

Public Risk Characterisation

In Australia, the chemical is known to be used in cosmetic (including leave-on and rinse-off) and household cleaning products. The chemical is also used in tattoo removal creams which require intradermal injection. The main route of public exposure is expected to be through the skin and inhalation from products applied as aerosols.

The chemical is currently listed on Schedule 5 of the SUSMP at concentrations greater than 5 %. At concentrations greater than 5 %, a number of warning statements, first aid instructions and safety directions relating to eye and skin irritation apply.

According to the CIR Expert Panel (CIR, 2013) formulations containing 0.83 - 20.04 % triethanolamine were irritating; however, detailed information regarding the formulation of these compounds was not reported. Also, the CIR (2013) reported that in studies using testing formulations containing 0.45 - 2.4 % of the chemical, no irritation was observed. Therefore, there is a concern for leave-on cosmetic products containing ≥ 2.5 % of the chemical.

Considering that application of the chemical to scarified skin results in skin irritation at lower concentrations than for un-scarified skin, there is a concern that the use of the chemical in tattoo removal procedures where the chemical is applied intradermally will result in skin irritation.

While the potential for nitrosamine formation is significantly less compared with secondary amines, there is a concern for the use of the chemical in cosmetic products under certain conditions, particularly in cosmetic products used as leave-on products. Under the EU Cosmetic directive restrictions, the use of the chemical is authorised in leave-on products at a maximum concentration of 2.5 % in the finished product (CosIng). Furthermore, for both leave-on and rinse-off products the following restrictions 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.

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 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.

The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation section**).

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemical in cosmetics and/or domestic products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through changes to classification and labelling.

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

It is recommended that an amendment to the current listing of the chemical in the SUSMP be considered. Matters to be taken into consideration include:

- a concern for irritation with leave on cosmetic products where the product contains ≥ 2.5 % triethanolamine;
- a concern for nitrosamine formation with use of the chemical in cosmetic products under certain conditions such as when used with nitrosating systems, particularly for leave-on cosmetic products;
- pH of the cosmetic product and concentration of triethanolamine salts affecting free triethanolamine levels; and
- the intradermal application of the chemical is more likely to result in skin irritation, such as when used in certain tattoo removal procedures requiring intradermal administration. Therefore, it is recommended that regulatory controls to prevent the use of intradermal application of the chemical in certain tattoo removal cosmetics be considered.

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]
Irritation / Corrosivity	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)

[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 the instruction on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal and ocular 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;

- 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

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