Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(9-octadecenylimino)di-2,1-ethanediyl]bis[.omega.-hydroxy-, (Z)-: Human health tier II assessment

01 July 2016

CAS Number: 26635-93-8

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.

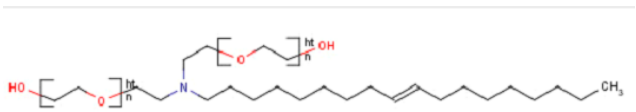
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	poly(oxy-1,2-ethanediyl), a,a'-[[(9Z)-9-octadecen-1-ylimino]di-2,1-ethanediyl]bis[?-hydroxy- poly(oxy-1,2-ethanediyl), a,a'-[(9-octadecenylimino)di-2,1-ethanediyl]bis[?-hydroxy-, (Z)- (Z)-octadec-9-enylamine, ethoxylated bis[?-hydrogenpoly(oxyethylene)]oleylamine PEG oleamine
Structural Formula	
Molecular Formula	(C2H4O)n(C2H4O)nC22H45NO2
Molecular Weight (g/mol)	443.71
SMILES	C(= {c}CCCCCCCCCN(OCCO)OCCO)CCCCCCCC

Import, Manufacture and Use

Australian

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was <100 tonnes.

The following Australian industrial use was reported under previous mandatory and/or voluntary calls for information – used to lower surface tension of liquids and promote cleaning, wetting and dispersion.

International

The following international uses have been identified through: Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; Handbook of Industrial Surfactants; Cosmetic Ingredient Review (CIR); and the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary.

The chemical has reported cosmetic uses, including:

- as a surfactant;
- as an emulsifying agent;
- as a cleansing, foam boosting and/or antistatic ingredient; and
- in hair dyes and tints (colour and bleaches).

The available information indicates that the chemical is used overseas in hair dyes up to a concentration of 3.5 %, and in skin moisturiser at a concentration up to 0.16 % (CIR, 2015).

The chemical has reported domestic uses, including:

- as a non-ionic surfactant;
- in paints, lacquer and varnish (and removers);
- in auto shampoo and car care products;
- in detergents; and
- in disinfectants.

Available North American databases do not give evidence for use of the chemical in domestic products, indicating the chemical is not likely to be widely available for domestic use.

The chemical has reported commercial uses, including:

- in degreasers;
- in cleaning/washing agents;
- in polishing agents;
- in detergents;
- as an emulsifier;
- in dyestuffs;
- in solvents;
- in metal treatment;
- as a stabiliser to prevent emulsion; and
- as an anticorrosive.

Restrictions

Australian

The chemical may be synthesised through processes which may result in 1,4-dioxane as an impurity, although it is expected to be removed to low levels. This impurity (listed under dioxane) is controlled through listing in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) in Schedule 6, with schedule labelling requirements applying above 100 ppm (Appendix G).

International

Trialkylamines, trialkanolamines and their salts are listed in EU Cosmetics Regulation 1223/2009 Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down and New Zealand Cosmetic Products Group Standard—Schedule 5: Components cosmetic products must not contain except subject to the restrictions and conditions laid down as follows

- maximum concentration of 2.5 % in leave-on products.

For use in leave-on and rinse-off products:

Do not use with nitrosating systems

- Minimum raw material purity: 99%
- Maximum secondary amine content: 0.5 % (applies to raw materials)
- Maximum nitrosamine content: 50 µg/kg
- Should not be used with nitrosating systems and should be kept in nitrite-free environments.

Existing Work Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

The chemical is a polyethylene glycol (PEG) derivative of the amine of oleic acid. The number of ethylene glycol (ethoxylate, AE) units can vary, with the number of ethoxylate units (average value of the two PEG chains) for cosmetic products ranging from 2–30 (PEG-2 oleamine, PEG-5 oleamine, PEG-6 oleamine, PEG-7 oleamine, PEG-10 oleamine, PEG-12 oleamine, PEG-14 oleamine, PEG-15 oleamine, PEG-20 oleamine, PEG-25 oleamine and PEG-30 oleamine (CIR, 2015).

Limited data are available for the chemical. The Cosmetic Ingedient Review (CIR) has used toxicity data on PEG-2 oleamine as part of a group assessment for 47 related ethoxylated fatty amines (including, but not limited to, PEG-n cocamine, PEG-n tallow amines and PEG-n hydrogenated tallow amines) (CIR, 2015). Where data for a specific toxic endpoint were not available for a PEG-n oleamine, toxicity data available for other ethoxylated fatty amines in this group have been included as part of a 'read across' methodology to determine what toxic effects may be reasonably expected from the use of the chemical. Toxicity data on the related ethoxylated fatty amines PEG-2 cocamine and PEG-15 cocamine (generic CAS No. 61791-14-8), PEG-8 stearamine and PEG-50 stearamine (generic CAS No. 9003-93-4), PEG-5 soyamine (generic CAS No. 61791-24-0), PEG-2 tallow amine, PEG-15 tallow amine and PEG-20 tallow amine (generic CAS No. 61791-26-2) and PEG-2 C13-C15 alkyl amine (CAS No. not available) have been quoted in the CIR report.

Toxicokinetics

No specific data were available for the chemical.

The chemical is a surfactant which may have low molecular weight species (< 1000 Da) and may be formulated with a high proportion of low molecular weight species < 500 Da; hence, absorption across biological membranes is possible.

The metabolism of the polyethoxylate groups in the chemical is anticipated to be similar to the metabolism of PEGs. PEGs are excreted usually unchanged in the urine and faeces after oral or intravenous exposure. The extent of metabolism depends on molecular weight; there is little or no metabolism of PEGs with molecular weights >5000 Da (eg, PEG-100). The metabolism of PEGs involves oxidation of the terminal alcohol groups to yield carboxylic acids, which is likely to be mediated by alcohol dehydrogenases or possibly sulfate conjugation of the terminal alcohol groups by sulfotransferases. The chemical may undergo C-hydroxylation or N-dealkylation to form corresponding metabolites (CIR, 2015).

Acute Toxicity

Oral

Based on the available data, the chemical is expected to have moderate acute oral toxicity in rats, but low acute oral toxicity in mice. Given that the mean lethal dose (LD50) in rats was <2000 for the majority of related ethoxylated fatty amines and in the absence of reliable data for the chemical, classification is considered warranted (refer **Recommendation** section). As the CAS number represents chemicals with a range of ethoxylate units, an exemption to classification based on the number of ethoxlate units cannot be established based on the available data. However, if data are available for a specific substance, the classification may be modified.

The following LD50 values are reported for unspecified PEG oleamines (Galleria):

- 200 mg/kg bw in rats; and
- 2000, 4230 and 5000 mg/kg bw in mice.

Data available on other ethoxylated fatty amines indicate that the group generally has low to moderate acute oral toxicity in rats (CIR, 2015):

- 750–1300 mg/kg bw for PEG-2 cocamine;
- 1200 mg/kg bw for PEG-15 cocamine;
- 1200–>2000 mg/kg bw for PEG-2 tallow amine;
- 630–1150 mg/kg bw for PEG-20 tallow amine; and

- 15 000 mg/kg bw for PEG-50 stearamine.

The degree of acute oral toxicity varies between chemicals in the group, but the relationship does not appear to be directly related to PEG chain length based on the information above.

Symptoms of toxicity in rats included (but were not limited to) hunched posture, piloerection, lethargy, abnormal gait, pallor (extremities), ptosis, diarrhoea, increased salivation, decreased respiratory rate and/or red staining around the eyes and nose (CIR, 2015).

Dermal

No data are available for the chemical. Based on the data available for other ethoxylated fatty amines, the chemical is expected to have low acute dermal toxicity (CIR, 2015).

The following acute dermal LD50 values have been reported in rabbits for other ethoxylated fatty acid amines (CIR, 2015):

- LD50 >2 mL/kg bw in two studies but <2 mL/kg bw in one study for PEG-20 tallow amine; and
- LD50 >1.5 g/kg bw for PEG-50 stearamine.

Observed effects included (but were not limited to) erythema (slight to moderate), oedema (slight to moderate), atonia (deficient muscle tone), coriaceousness (leather-like appearance), desquamation, fissuring, eschar formation, exfoliation, subcutaneous haemorrhage and/or hyperthermia (CIR, 2015).

Inhalation

No data are available for the chemical or other ethoxylated fatty amines.

Corrosion / Irritation

Respiratory Irritation

No data were available for the chemical or other ethoxylated fatty amines.

Skin Irritation

Based on the available information, the chemical is expected to be irritating to skin. Although the extent of irritation cannot be determined, in the absence of data based on the results for other ethoxylated fatty amines and the known irritant responses of surfactants, hazard classification is recommended. As the CAS number represents chemicals with a range of ethoxylate units, an exemption to classification based on the number of ethoxlate units cannot be established based on the available data. However, if data are available for a specific substance, the classification may be modified.

No skin irritation data are available for the chemical. The data available on other ethoxylated fatty amines indicate that skin irritation potential of chemicals in this class may vary from mildly irritating to severely irritating (PEG-2 cocamine). The CIR concluded that the irritation potential of these fatty amines is consistent with the surface-active properties that are characteristic of surfactants (CIR, 2015).

In a study in New Zealand White rabbits (six), semiocclusive patches of 0.5 ml PEG-2 cocamine (concentration not stated) were applied to intact skin for a period of 4 hours. The primary irritation index values (PIIs) were 6.2 at patch removal, 7.2 at 24 hours, and 7.3 at 48 hours. Eschar and necrotic areas were observed at both the 24 and 48 hours readings. In other studies in which PEG-2 cocamine was applied to abraded and intact rabbit skin, the reported PIIs were 2.4–3.9, based on observed severe erythema. PEG-15 cocamine was reported to be a mild irritant with a reported PII of 1.4 (CIR, 1999).

In acute dermal toxicity studies with PEG-20 tallow amine, slight to marked erythema, atonia and coriaceousness, slight to moderate oedema, desquamation and fissuring, eschar formation, exfoliation, subcutaneous haemorrhage and hyperthermia were observed. Signs of skin irritation were observed in animals during skin sensitisation testing with PEG-2 tallow amine (CIR, 2015).

Eye Irritation

Based on the limited available information, the chemical is considered to be an eye irritant warranting hazard classification. As the CAS number represents chemicals with a range of ethoxylate units, an exemption to classification based on the number of ethoxylate units cannot be established based on the available data. However, if data are available for a specific substance, the classification may be modified.

The chemical is reported as causing severe eye irritation in rabbits in a standard Draize test (Galleria). No study details were available to confirm the severity of effects or level of ethoxylation.

In two separate studies in New Zealand White rabbits, PEG-2 cocamine produced eye irritation effects. Irritation scores up to 64.5 (out of 110) were reported with severe effects persisting after 7 days. In a similar study with PEG-15 cocamine, corneal opacity and conjunctival inflammation, swelling, ocular discharge and decreased iridic response to light were observed. Irritation scores up to 42 were reported (CIR, 1999).

Sensitisation

Skin Sensitisation

Limited data are available. Whilst the chemical (with an average of two ethoxylate units) was negative in a guinea pig maximisation test (GPMT), there was some evidence of sensitisation for a related ethoxylate unsaturated alkyl amine. The presence of a double bond in the alkyl chains (unsaturation) may contribute to a sensitising potential. The available data do not warrant hazard classification.

The PEG-2 oleamine was not found to induce dermal sensitisation in guinea pigs when tested using a similar method to OECD Test Guideline (TG) 406 (guinea pig maximisation test method). The first induction treatment (intradermal) on day 1 used a concentration of 0.1 % of PEG-2 oleamine in corn oil; the second topical induction (day 8) used a concentration of 10 % of PEG-2 oleamine (in ethanol : water). Topical challenge (on day 22) used a 1% concentration of PEG-2 oleamine in acetone. Local skin reactions were observed at the injection sites of some animals on study days 21-25; discrete erythema was observed in 2 out of 10 animals 48 hours after the topical challenge. The test material did not cause skin sensitisation under the conditions of the study (CIR, 2015).

A related chemical PEG-2 tallow amine tested negative for skin sensitisation in guinea pigs but was positive for skin sensitisation potential when tested in mice (local lymph node assay - LLNA). The LLNA showed that PEG-2 tallow amine caused significant skin irritation in mice; however, the magnitude of the response (maximum SI was 125.9) indicated that the positive sensitisation result could not be wholly attributed to skin irritation as a confounding factor (CIR, 2015).

Observation in humans

Data available on mixtures containing PEG-15 cocamine indicated no sensitisation potential in humans following repeated dermal exposure to concentrations up to 2.9 % (CIR, 2015).

Repeated Dose Toxicity

Oral

No data are available for the chemical. While related chemicals cause gastrointestinal irritation following repeated oral dosing, severe systemic toxicity is not observed at low to moderate doses.

Data are available for some ethoxylated fatty amines, and suggest that most of the toxicity associated with repeated oral dosing is associated with inflammatory responses in the gastrointestinal tract (likely due to repeated irritation—local effects). However, cataracts were observed in rats that received a related chemical, PEG-2 C13-C15 alkyl amine at oral doses of 30 mg/kg bw/day and above.

In a 90 day study, Wistar rats (n = 25/sex/dose) were administered a related chemical, PEG-2 tallow amine in the diet at concentrations of 0, 170, 500 or 1500 ppm (approximately 0, 15, 50 or 150 mg/kg bw/day). Another group (n = 10/sex) was administered 4500 ppm of the test material. Clinical symptoms of toxicity included lethargy and hair loss at 4500 ppm. The no observed effect level (NOEL) was 500 ppm (approximately 50 mg/kg bw/day) based on decreased bodyweight gain and macroscopic and microscopic findings in the gastrointestinal tract (yellow colouration of the stomach and bowel contents, thickening and yellow colouration of the small intestine mucosa and mesenteric nodes, engorgement of the villi and lamina propria of the small intestine with swollen foamy sudanophilic macrophages) at 1500 ppm. The same chemical, PEG-2 tallow amine, was administered to beagle dogs (n = 4/sex/dose) in the diet at doses of 0, 13, 40 or 120 mg/kg bw/day for 90 days. The NOEL was reported as 13 mg/kg bw/day; however, the basis for the NOEL was not reported (CIR, 2015).

Sprague Dawley (SD) rats (20/sex/dose) were administered a related chemical, PEG-2 C13-C15 alkyl amine, at doses of 0, 15, 30 or 150 mg/kg bw/day via oral gavage for 90 days. Clinical symptoms of toxicity were observed at doses of 30 mg/kg bw/day and above. These included increased mortality, blood crust/red discharge from nose, dyspnoea, rhinorrhoea, opaque eyes, redness, hunched posture, thin, urine stains, rough hair coat, desquamation and/or increased incidence of alopecia. Cataracts were observed at doses of 30 mg/kg bw/day and above. Desquamation/alteration of the non-glandular stomach mucosa was observed at doses of 30 mg/kg bw/day and above. The no observed adverse effect level (NOAEL) was 15 mg/kg bw/day (CIR, 2015).

In a 90 day study, SD rats (n = 10/sex/dose) were administered a related chemical, PEG-15 tallow amine in the diet at concentrations of 0, 500, 1500 or 4500 ppm (approximately 0, 33/40, 99/123 or 292/357 mg/kg bw/day in males/females). Clinical symptoms of toxicity included soft stools and reduced bodyweight and bodyweight gain at 4500 ppm. The NOAEL was 500 ppm (approximately 33/40 mg/kg bw/day) based on microscopic findings in the gastrointestinal tract (hypertrophy and vacuolation of histiocytes in lamina propria of the ileum and jejunum, sinus histiocytosis and accumulation of macrophage aggregates in the mesenteric lymph nodes) at 1500 ppm and above (CIR, 2015).

Dermal

No data are available for the chemical. The chemical is not expected to cause significant systemic toxicity following repeated dermal exposure based on data for related chemicals.

The available data for other ethoxylated fatty amines (PEG-2 tallow amine and PEG-20 tallow amine) suggest that they have low dermal toxicity following repeated dosing. In 28-day dermal studies conducted in rabbits, the effects were generally localised irritant effects on the skin at treatment sites, and included epidermal and keratin layer thickening, moderate to severe erythema and oedema, slight to moderate atonia, slight to marked desquamation, leather-like appearance and/or slight to severe fissuring (CIR, 2015).

Inhalation

No data were available for the chemical or other ethoxylated fatty acid amines.

Genotoxicity

No data are available for the chemical. Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies for other ethoxylated fatty amines, the chemical is not considered to be genotoxic.

The in vitro genotoxicity data for ethoxylated fatty amines indicated mostly negative results (CIR, 2015):

- PEG-2 tallow amine, PEG-15 tallow amine, PEG-20 tallow amine, and PEG-8 stearamine were negative in bacterial reverse mutation assays in *Salmonella typhimurium* strains;
- PEG-20 tallow amine was negative in an unscheduled DNA synthesis assay in rat hepatocytes; and
- PEG-20 tallow amine was negative in a mouse lymphoma mutation assay on $TK^{+/-}$ L5178 cells.

However, PEG-20 tallow amine showed a concentration-dependent increase in chromosome aberrations in Chinese hamster ovary cells in the presence of metabolic activation.

In vivo genotoxicity studies conducted on ethoxylated fatty amines are considered negative (CIR, 2015):

In a mouse micronucleus assay (single gavage dose of 10860 mg/kg bw), PEG-2 tallow amine showed a statistically significant increase in the number of micronucleated polychromatic eryrthocytes after 24 hours. However, numbers observed were within historical controls and no increase was observed after 48 and 72 hours. A statistically significant increase in the polychromatic to normochromatic erythrocyte ratio that was observed at 24, 48 and 72 hours provided evidence of exposure to the bone marrow.

The PEG-15 tallow amine gave negative results in a mammalian micronucleus assay (species and exposure route not specified) at 100 mg/kg and PEG-20 tallow amine was negative in a cytogenicity study in rats when dosed via gavage at 39, 130 or 390 mg/kg bw/day.

Carcinogenicity

No data were available for the chemical or other ethoxylated fatty amines. The chemical is a mixture of tertiary alkyl amines that may also contain some primary and secondary amines. Nitrosamines could be produced in formulations that contain nitrosating agents. The nitrosation of the tertiary amine requires the cleavage of the carbon-nitrogen bond of one of the alkyl groups attached to the nitrogen atom and is, therefore, less likely than nitrosation of primary or secondary amines. The rates and the nature of these processes depend significantly on the structure of the tertiary amine. In general, tertiary alkanolamines and other tri-alkyl amines may be used in many commercial formulations of interest without concern for nitrosamine formation. Based on structural features, the chemical is not expected to have unusually high reactivity towards nitrosation. (SCCS, 2012).

Reproductive and Developmental Toxicity

No data are available for the chemical. Health effects seen for related chemicals appear to be secondary to maternal toxicity, which is attributable to gastrointestinal irritation.

Data are available for other ethoxylated fatty acid amines; PEG-15 tallow amine and PEG-2 cocamine. Treatment-related effects observed in rats during reproduction and developmental studies included decreased live litter size, decreased implantation sites, lower postnatal survival, increased implantation sites that were unaccounted for and/or decreased mean number of pups born (CIR, 2015). Effects on development were generally observed in the presence of maternal toxicity; except for a two generation developmental and reproduction toxicity screening study in rats using PEG-15 tallow amine (CIR, 2015).

Sprague Dawley (SD) rats (n = 20/sex/group) were administered PEG-15 tallow amine in the diet a concentrations of 0, 100, 300 or 1000 ppm. In this two generation study, parental (F0) animals received the diet for at least 70 days prior to mating, throughout mating and/or gestation until scheduled termination (post natal day 21 for females). The first generation (F1) animals received the diet for at least 80 days prior to mating, throughout mating and/or gestation until scheduled termination (post natal day 21 for females). Effects in the F0 and F1 animals reported as being potentially related to treatment included litter loss, increased mean number of unaccounted for implantation sites, decreased mean number of pups born, live litter size and post natal survival. Effects were not observed in the F2 generation, and the only effect that was reported as statistically significant and outside the historical control range was an increased mean number of unaccounted for implantation sites. The reported NOAEL for systemic effects and the LOAEL for developmental and reproductive effects was the highest dose of 1000 ppm (approximately 65–66 mg/kg bw/day), and the NOAEL for developmental and reproductive effects was 300 ppm, or approximately 15–17 mg/kg bw/day (CIR, 2015).

Risk Characterisation

Critical Health Effects

Based on the available data, the potential critical health effects identified for the chemical are: local effects (skin and eye irritation) and systemic acute effects. If ingested, health effects attributable to gastrointestinal irritation are seen.

There are insufficient data to make conclusions on the long term systemic effects associated with the chemical.

Public Risk Characterisation

The chemical is reported to be used in Australia to reduce surface tension of liquids and promote cleaning, wetting and dispersion, indicating its use in cosmetics. The chemical is reported to be used in cosmetic products overseas at concentrations up to 3.5 % (CIR, 2015). Based on international data, widespread use in domestic products is not expected.

Overall, the chemical is not considered to pose an unreasonable risk to public health, based on the nature of the hazard (skin and/or eye irritation) associated with the chemical and that the chemical is expected to be used at concentrations up to 3.5 % only. Whilst there is limited evidence of long term systemic effects given the low concentrations used and primary use in hair dye products, the risk is considered to be low.

Occupational Risk Characterisation

Given the critical local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise exposure are implemented. As the chemical is a mixture of various related components, there is the potential for variability regarding the level of skin and/or eye irritation that may be expected. 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 the appropriate controls.

The data available support hazard classification of the chemical (refer to **Recommendation** section).

NICNAS Recommendation

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

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP).

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 and environmental hazards.

Whilst the CAS number represents chemicals with a range of ethoxylate units, an exemption to classification based on the number of ethoxylate units cannot be established based on the available data. However, if data are available for a specific substance, the classification may be modified.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Irritating to eyes (Xi; R36) Irritating to skin (Xi; R38)	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)

[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 instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal or 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 that could minimise the risk include, but are not limited to:

- 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 help meet 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 is 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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Last update 01 July 2016

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