Australian Government

Department of Health

National Industrial Chemicals Notification and Assessment Scheme

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)



HUMAN HEALTH TIER II ASSESSMENT FOR

Tetraethylammonium salts

Chemical name in AICS	CAS Number
Ethanaminium, N,N,N-triethyl-, chloride	56-34-8
Ethanaminium, N,N,N-triethyl-, bromide	71-91-0

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take four years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

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.

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

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

Disclaimer

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ACRONYMS & ABBREVIATIONS

ACTOR Aggregated Computational Toxicology Resource (US)

AICS Australian Inventory of Chemical Substances

ATSDR Agency for Toxic Substances and Disease Registry (US)

bw bodyweight

CAS Chemical Abstracts Service CFR Code of Federal Regulations (US)

CHO Chinese hamster ovary

CosIng Cosmetic Substances and Ingredients database (EU)

d day

DNA Deoxyribonucleic acid EC European Commission

EC3 Estimated concentration to produce a three-fold increase in lymphocyte proliferation

ECHA European Chemicals Agency

ESIS European Chemical Substances Information System

EU European Union

EU RAR European Union Risk Assessment Report FDA Food and Drug Administration (US) FSANZ Food Standards Australia and New Zealand

g gram

g/mol grams per mole

GHS Globally Harmonized System of Classification and Labelling of Chemicals*

GLP Good Laboratory Practice
GMP Good Manufacturing Practice
GPMT Guinea pig maximisation test

h hour

HGPRT hypoxanthine guanine phosphoribosyltransferase

HPV high production volume

HSDB Hazardous Substances Data Bank

HSIS Hazardous Substances Information System
HVICL High Volume Industrial Chemicals List
IARC International Agency for Research on Cancer

INCHEM International Programme on Chemical Safety (also known as IPCS)

INCI International Nomenclature of Cosmetic Ingredients

ip intraperitoneal

IRIS Integrated Risk Information System (US)

IUCLID International Uniform Chemical Information Database

iv intravenous kg kilogram L litre

LC50 median lethal concentration

LD50 median lethal dose

LCLo lowest published lethal concentration

LDLo lowest published lethal dose LLNA local lymph node assay

LOAEL lowest observed adverse effect level

LOEL lowest observed effect level

m³ cubic metre mg milligram

mg/cm³ milligrams per cubic centimetre

mg/kg bw/d milligrams per kilogram bodyweight per day

min minute
mL millilitre
μg microgram
μL microlitre

(m)SDS (material) Safety Data Sheet

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NIOSH National Institute for Occupational Safety and Health (US)

NOAEC no observed adverse effect concentration

NOAEL no observed adverse effect level NOEC no observed effect concentration

NOEL no observed effect level

NOHSC National Occupational Health and Safety Commission

NTP National Toxicology Program (US)

OECD Organisation for Economic Cooperation and Development

OEL occupational exposure limit

PCBU person conducting a business or undertaking

PEL permissible exposure limit

PND postnatal day ppb parts per billion

PPE personal protective equipment

ppm parts per million

QSAR Quantitative Structure-Activity Relationship

REACH Registration Evaluation Authorisation of Chemicals (ECHA)

SD Sprague Dawley

SIAP SIDS Initial Assessment Profile (OECD)
SIAR SIDS Initial Assessment Report (OECD)
SIDS Screening Information Data Set (OECD)
SMILES simplified molecular-input line-entry system
SPIN Substances in Preparations in the Nordic Countries

STEL short-term exposure limits

STV short-term value

SUSMP Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)

TCLo lowest published toxic concentration

TDLo lowest published toxic dose

TEEL temporary emergency exposure limits
TSCA Toxic Substances Control Act (US EPA)

TG test guideline

TGA Therapeutic Goods Administration

TLV threshold limit values TWA time weighted average

UN United Nations

US United States of America

US EPA United States Environmental Protection Agency

WHS Work, Health and Safety

wt weight

w/w weight per weight

Glossarv

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:

Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and

Part 2: IPCS Glossary of Key Exposure Assessment Terminology.

The IPCS Risk Assessment Terminology can be accessed at:

http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

*Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs rev03/03files e.html

**The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/publication/poisons-standard-susmp

Chemical Name in AICS (Including Synonyms)	CAS Number	Structural Formula		Molect Formula	ular Weight (g/mol)
Ethanaminium, N,N,N-triethyl-, bromide	71-91-0				
tetraethylammonium bromide (TEAB)		H_3C O	r.	C8H20N.Br	210.10
Ethanaminium, N,N,N-triethyl-, chloride	56-34-8				
tetraethylammonium chloride (TEAC)		H ₃ C CH ₃	٢	C8H20N.Cl	165.70

Grouping Rationale

The chemicals in this group are tetraethylammonium compounds with the cation being a quaternary ammonium group, with chloride and bromide counterions. These chemicals share structural and functional similarities and have similar physicochemical properties and biodegradability. A similar health hazard profile is expected subject to the toxicological differences of the anions.

The chemicals in this group have similar reported uses.

The following acronyms and their corresponding CAS numbers will be used in this assessment:

- TEAC (CAS No. 56-34-8); and
- TEAB (CAS No. 71-91-0).

Import, Manufacture and Use

Australian

The National Pollutant Inventory (NPI) holds data for all sources of the chemicals in Australia.

Safety data sheets (SDS) indicate that the chemical has Australian site-limited uses, including as a:

- chemical intermediate; and
- phase-transfer catalyst.

These chemicals also have reported non-industrial therapeutic uses.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and World Health Organisation International Programme on Chemical Safety document (IPCS, 1999).

The chemical, TEAB has reported domestic uses, as a:

- binding agent for paints and adhesives; and
- filling agent for insulation materials.

These chemicals have reported commercial uses, including in:

- oil and water based hydraulic fracturing; and
- lubricants.

These chemicals have reported site-limited uses, as:

- chemical intermediates;
- intermediate in petroleum products; and
- phase-transfer catalysts.

Non-industrial uses of the chemicals as therapeutic agents and as intermediates in pesticides have been reported internationally.

Restrictions

Australian

These chemicals are covered by the group entry for QUATERNARY AMMONIUM COMPOUNDS in Schedules 5 and 6 and by TETRAETHYLAMMONIUM entry in Schedule 4 of the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, 2019):

Schedule 6:

'QUATERNARY AMMONIUM COMPOUNDS except:

- a) when separately specified in these Schedules;
- b) when included in Schedule 5;
- c) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- d) in preparations containing 5 per cent or less of such quaternary ammonium compounds.'

Schedule 5:

'QUATERNARY AMMONIUM COMPOUNDS in preparations containing 20 percent or less of quaternary ammonium compounds except:

- a) when separately specified in these Schedules;
- b) dialkyl or dialkoyl quaternary ammonium compounds where the alkyl or alkoyl groups are derived from tallow or hydrogenated tallow or similar chain length (C16/C18) sources; or
- c) in preparations containing 5 per cent or less of such quaternary ammonium compounds.'

Schedule 4:

"TETRAETHYLAMMONIUM"

Schedule 6 chemicals are described as 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'. Schedule 6 chemicals are labelled with 'Poison' (SUSMP, 2019).

Schedule 5 chemicals are described as 'Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.' Schedule 5 chemicals are labelled with 'Caution' (SUSMP, 2019).

Schedule 4 chemicals are described as '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.' Schedule 4 chemicals are labelled with 'Prescription Only Medicine' or 'Prescription Animal Remedy' (SUSMP, 2019).

International

TEAB and TEAC are listed on the following (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain:

- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient 'Hotlist'); and
- Association of Southeast Asian Nations (ASEAN) Cosmetic directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

Existing Work Health and Safety Controls

These chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available for any chemical in this group.

International

The following exposure standards are identified for TEAC and TEAB (Galleria Chemica):

Temporary Emergency exposure Limits (TEELs) defined by the US Department of Energy (DOE) for the chemical are reported as:

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TEEL-1= 0.67-1.1 \text{ mg/m}^3;
TEEL-2= 1.3-12 \text{ mg/m}^3;
TEEL-3= 7.6-43 \text{ mg/m}^3.
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Health Hazard Information

The toxicity of the tetraethylammonium salts in this assessment is considered to be largely due to the presence of the tetraethylammonium cation. Toxicological information of the anions is reported where relevant.

The available toxicity data for TEAC and TEAB are used in this assessment and, unless specifically stated, should be read-across for all chemicals in this groups to represent the toxicity of the tetraethylammonium cation.

Toxicokinetics

Limited data are available for specific chemicals in this group. However, quaternary ammonium compounds are known to be poorly absorbed by the oral route (IPCS, 1999).

Acute Toxicity

Oral

The chemicals have low to moderate oral acute toxicity based on results from animal tests following oral exposure. The median lethal dose values (LD50) for TEAC and TEAB are >2000 mg/kg bw in rats.

In an acute oral toxicity study, albino rats (n=155/sex) were given 2630 mg/kg of TEAC (40.6 % test substance in water) once by gavage. Mortality in 50 % of treated animals was recorded within 10–30 minutes of exposure and was reported to be due to respiratory failure. Observed clinical signs included tremors, incoordination and flaccid prostration. The LD50 was considered to be >2000 mg/kg bw in rats (REACHa).

In an acute oral toxicity study conducted according to the OECD Test Guideline (TG) 401, Sprague Dawley (SD) rats (n=5/sex/dose) were given TEAB by gavage as single doses of 1800, 2400 or 3200 mg/kg bw. Mortality observed was 0/10 at 1800 mg/kg bw; 1/5 males and 2/5 females at 2400 mg/kg bw; and 5/5 males and 3/5 females at 3200 mg/kg bw. Observed effects included lethargy, tremors, convulsions, coma, laboured breathing, diarrhoea, unbalanced gait and bloody nose or eye encrustation. These signs were reported to be reversible in all surviving animals by day 3 to day 14 of the observation period. Gross pathological examination showed hyperaemia, erosion of stomach, petechiae (tiny, circular patches on the skin or in a mucous membrane), bloody gastrointestinal content, renal hyperaemia, mottled kidneys and autolysis. The LD50 was calculated to be >2000 mg/kg bw (REACHb).

In a study based on OECD TG 423, female SD rats (n=3/dose) were given 10 mL of TEAB in water by gavage at doses of 300 or 2000 mg/kg bw. No mortality was observed at any treatment dose. Clinical signs observed at

2000 mg/kg bw were diarrhoea, reduced locomotor activity and ataxic gait. An LD50 of >2000 mg/kg bw was determined (REACHb).

Dermal

The chemicals have low acute toxicity based on limited results from animal tests following dermal exposure. The median lethal dose (LD50) for TEAB in rats is >2000 mg/kg bw.

In an acute dermal toxicity study (OECD TG 402) in SD rats, TEAB was occlusively applied to the dorsal skin at 2000 mg/kg bw for 24 hours. No mortality occured. An LD50 value of >2000 mg/kg bw was determined (REACHb).

Inhalation

No data are available for the chemicals.

Irritation / Corrosivity

Skin Irritation

Based on the available data, the chemicals in this group are not considered to be irritating to skin.

In a skin irritation study (OECD TG 404) in New Zealand White (NZW) rabbits, 0.5 gm of TEAB (purity: 99.23 %) was applied on shaved skin semiocclusively, for 4 hours. The rabbits were observed for up to 72 hours following treatment. No clinical signs were observed. The primary dermal irritation index (PDII) was 0. No signs of skin reaction or systemic toxicity were reported (REACHb).

Eye Irritation

Based on the available data from guideline studies, the chemicals are considered to cause eye irritation and warrant hazard classification for all chemicals in this group (see **Recommendation** section).

In an Epiocular eye irritation test (OECD TG 492; RhCE test), neat TEAC was tested for eye irritation in a human keratinocytes cell system for 6 hours \pm 15 minutes. Cell viability of 35.9 % was recorded. Since the mean tissue viability after exposure to the chemical was below 60 %, the chemical is considered to be irritating to the eyes (REACHa).

In an acute eye irritation study conducted according to OECD TG 405, female New Zealand White (NZW) rabbits (n=3) were treated with 72 mg of TEAB in one eye and observed for 7 days following treatment. Reversible conjunctival redness and swelling was observed in one animal. No corneal injury was observed. Mean scores of 0/3, 0/3 and 1.3/3 were reported for corneal opacity, iridial lesions and conjunctival lesions, respectively. All effects were fully reversed by day 7 (REACHb).

In an RhCE (OECD TG 492) study, $50~\mu L$ of TEAB was tested for eye irritation potential in human keratinocytes cell system for 6 hours \pm 15 minutes. Cell viability of 29.3 % was recorded. Since the mean tissue viability after exposure to the chemical was below 60 %, the chemical is considered to be irritating to the eyes (REACHb).

Sensitisation

Skin sensitisation

Based on the available in vivo, in vitro and in silico information, the chemicals in this group are not likely to be skin sensitisers. In chemico and in vitro guideline studies covering the first 2 key events of the adverse outcome pathway (AOP) for skin sensitisation were negative.

In a skin sensitisation study conducted according to OECD TG 406 (Buehler test), female Pirbright-White guinea pigs (n=30/group) were topically induced with TEAB at 4 % for 6 hours, followed by a second induction on day 8 and a third induction on day 15. Animals were then challenged with the chemical at 1 % concentration 14 days later (day 29). Slight to severe oedema, well-defined to severe erythema, and necrotic areas were observed in the treated skin of experimental animals after the second induction dose (day 15) but no responses were seen at challenge. The chemical was not considered to have sensitisation potential (REACHb).

The (Q)SAR modelling for skin sensitisation potential using the OECD QSAR Toolbox (version 3.4) indicated that TEAC is predicted not to be sensitising to the skin of female CBA mouse (REACHa).

Repeat dose toxicity

Oral

The results from a single repeated dose toxicity study summarised below indicate minimal changes in the liver weight and minor haematological changes. These do not meet the classification criteria for repeated dose toxicity.

In a 28-day study conducted according to OECD TG 407, TEAB was administered orally to SD rats (n= 36/sex/dose) at 0, 250, 500 or 1000 mg/kg bw/day for 28-days followed by a 14-day recovery period. No mortalities were recorded. Haematological findings showed significant increase in neutrophil values for males from the 500 and the 1000 mg/kg dose groups and for females from 1000 mg/kg bw/day dose groups. A decrease in lymphocytes values was seen in males at 1000 mg/kg. Statistically significant changes observed in males included decreased relative weights of liver at 250 and 1000 mg/kg bw/day; decreased relative kidney and brain weights at 250, 500 and 1000 mg/kg bw/day; decreased relative testes weights at 250 mg/kg bw/day and decreased prostate and seminal vesicle weights at 1000 mg/kg bw/day. Statistically significant changes observed in females included increased relative liver weights at 250, 500 and 1000 mg/kg bw/day; increased relative kidney weights at 500 and 1000 mg/kg bw/day and increased relative uterus weights at 500 mg/kg bw/day. Other effects observed included minimal focal to multifocal perportal mononuclear cells infiltation in liver; tubular vacuolation and mineralisation on the kidneys; minimal and diffuse dilatation of zona reticularis in the adrenals; luminal dilatation in the uterus; presence of ectopic thymus in thyroid; multifocal glandular dilatation in stomach; vacuolation of acinar cells of pancreas; presence of Rathke's pouch in the pituitary in males and females in the control and all treatment groups. No severe dose dependent effects were reported. A no observed adverse effect level (NOAEL) of 1000 mg/kg bw/day was proposed based on absence of major adverse effects at the highest dose (REACHb).

In a 63-day oral gavage study conducted in accordance with OECD TG 422, Wistar rats (n=13/sex/dose) were administered TEAB at doses of 0, 250, 500 or 750 mg/kg bw/day. No mortality or morbidity was observed. Significant decrease in percent body weight change at 500 mg/kg bw/day, increased cholesterol at 750 mg/kg bw/day and increased spleen weight were observed in treated females.

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the available in vitro and in silico data, the chemicals in this group are not considered to be genotoxic.

Negative results were observed in a bacterial reverse mutation assay (OECD TG 471) in *Salmonella typhimurium* strains TA98 and TA100 for TEAB at concentrations of 0.01, 1, 5 or 20 mg/plate, with and without metabolic activation (REACHa; REACHb).

In silico

(Q)SAR modelling for genetic toxicity using the OECD QSAR Toolbox (version 3.4) indicated that there were no alerts for mutagenicity for any chemical in this group (REACHa).

Carcinogenicity

No data are available.

Reproductive and developmental toxicity

Reproductive toxicity

No data are available for reproductive or developmental toxicity. Based on the limited information available for the repeat dose toxicity, the chemicals are not expected to elicit specific reproductive or developmental toxicity.

In the 28-day repeated-dose oral toxicity study described above, TEAB was administered orally to SD rats (n= 36/sex/dose) at 0, 250, 500 or 1000 mg/kg bw/day for 28-days followed by a 14-day recovery period. Statistically significant changes observed in males included decreased testes weights at 250 mg/kg bw/day and decreased prostate and seminal vesicle weights at 1000 mg/kg bw/day. Statistically significant changes observed in females included increased uterus weights at 500 mg/kg bw/day. No related gross pathological and histopathological changes were seen in these organs. The NOAEL for reproductive effects was 1000 mg/kg bw/day (REACHb).

Risk Characterisation

Critical Health Effects

The critical health effect for risk characterisation includes eye irritation.

Public Risk Characterisation

Although the use of chemicals in this group in domestic products in Australia is not known, the chemicals are reported to be used in domestic products overseas (see import, manufacture and use section).

Considering the range of domestic products that may contain the chemicals, the main routes of public exposure are expected to be through the skin, inhalation from products applied as aerosols and potential exposure through oral products.

The chemicals are currently listed on Schedule 5 and 6 of the SUSMP for 'QUATERNARY AMMONIUM COMPOUNDS' and on Schedule 4 for 'TETRAETHYLAMMONIUM'. The Schedule of entry should preclude use of these chemicals in industrial use, including cosmetic and domestic products; however, it is probable that this restriction may not be observed.

Currently, there are no restrictions in Australia on using these chemicals in concentrations below 5 %, including in cosmetics or domestic products. However, cosmetic/domestic products containing the chemicals at low concentrations (<5 %) are not considered to pose an unreasonable risk to public health.

Provided that normal precautions are taken to avoid prolonged skin contact and with available controls for quaternary ammonium compounds, cosmetic/domestic products containing the chemicals are not considered to pose an unreasonable risk to public health.

Occupational Risk Characterisation

During product formulation, oral, dermal, ocular and inhalation exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical local health effect, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise ocular and inhalation exposure are implemented. The chemicals 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 an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

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

Consideration should be given to revision of the schedule 4 entry for TETRAETHYLAMMONIUM to limit its

use to therapeutics only.

Regulatory Control

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2019).

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

A	pproved Criteria (HSIS)ª	GHS Classification
Irritation / Corrosivity No	t Applicable	Causes eye irritation - Cat. 2B (H320)

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

Advice for industry

Control measures

Control measures to minimise the risk from oral, dermal, inhalation and ocular exposure to the chemicals 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 chemicals are used. Examples of control measures that could minimise the risk include, but are not limited to:

- 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 chemicals.

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 chemicals 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.

^{*} Existing Hazard Classification. No change recommended to this classification.

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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 these chemicals has not been undertaken as part of this assessment.

References

Cosmetic Ingredients & Substances (CosIng) Database. European Commission. Accessed June 2019 at http://ec.europa.eu/consumers/cosmetics/cosing/

Galleria Chemica. Accessed June 2019 at http://jr.chemwatch.net/galleria/

Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations 2009. Third edition. Accessed November 2019 at http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

Gruhzit OM, Fisken RA and Cooper BJ. (1948) Tetraethylammonium chloride. Acute and chronic toxicity in experimental animals. Journal of Pharmacology and Experimental Therapeutics 92 (2):103-107.

International Programme on Chemical Safety (IPCS) 1999. Quaternary ammonium. Accessed June 2019 at http://www.inchem.org/documents/pims/chemical/pimg022.htm

National Pollutant Inventory (NPI). Accessed June 2019 at http://www.npi.gov.au/index.html

Organisation for Economic Co-operation and Development List of High Production Volume chemicals 2007 (OECD HPV). Accessed June 2019 at http://www.oecd.org/chemicalsafety/risk-assessment/33883530.pdf

Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary. Accessed June 2019 at http://www.ctfa-gov.org/jsp/gov/GovHomePage.jsp

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACHa). Registration dossier for Tetraethylammonium chloride(CAS No. 56-34-8). Accessed June 2019 at https://echa.europa.eu/registration-dossier/-/registered-dossier/20036

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACHb). Registration dossier for Tetraethylammonium bromide(CAS No. 71-91-0). Accessed June 2019 at https://echa.europa.eu/registration-dossier/-/registered-dossier/19226

Safe Work Australia. Hazardous Chemical Information System (HCIS). Accessed June 2019 at http://hcis.safeworkaustralia.gov.au/HazardousChemical

Substances in Preparations in Nordic countries (SPIN) database. Accessed June 2019 at http://www.spin2000.net/spinmyphp/

The Poisons Standard October 2019. The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) No. 25. Accessed November 2019 at https://www.tga.gov.au/publication/poisons-standard-susmp

The United States (US) Environmental Protection Agency's (EPA) Aggregated Computational Toxicology Resource (ACToR). Accessed June 2019 at https://actor.epa.gov/actor/home.xhtml

US National Library of Medicine's Hazardous Substances Database (HSDB). National Library of Medicine. Accessed June 2019 at http://toxnet.nlm.nih.gov