Tertiary aliphatic (C8-12) amines: Human health tier II assessment

27 November 2014

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Decanamine, N,N-didecyl-	1070-01-5
1-Dodecanamine, N,N-didodecyl-	102-87-4
1-Octanamine, N,N-dioctyl-	1116-76-3
Amines, tri-C8-10-alkyl	68814-95-9

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

Grouping Rationale

The chemicals in this group are structurally related tertiary amines substituted with linear aliphatic chains that range from 8 to 12 carbon atoms in length.

The chemicals in this group have average molecular weights between 353 and 522 Da. Although the molecular weight of most of the chemicals in this group is less than 500 Da, high dermal absorption is not expected due to the high log Kow > 7.

Import, Manufacture and Use

Australian

The following Australian industrial use was reported under previous mandatory and/or voluntary calls for information:

The chemical (CAS No. 68814-95-9) has reported site-limited use as a solvent.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation and Authorisation of Chemicals (REACH) dossiers; Galleria Chemica; the European Commission Cosmetic Ingredients and

Substances (CosIng) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and the OECD High Production Volume chemical program (OECD HPV).

Tridodecylamine (CAS No. 102-87-4) is included in the CosIng database and US Personal Care Products Council INCI directory with the identified cosmetic function of an antistatic agent. There are no documented uses of the chemical in cosmetics in various databases in the United States (ed. Bailey 2011; US Department of Health and Human Services, American Cleaning Institute), or a survey of ingredients used in fragrance products in Europe (IFRA 2011).

The chemical (CAS No. 68814-95-9) has reported commercial use including:

- in pH regulators;
- in flocculants;
- as precipitants; and
- as neutralisation agents.

The chemicals have reported site-limited use including:

- as intermediates (CAS No. 102-87-4); and
- as corrosion inhibitors (CAS No. 68814-95-9).

The are no reported uses for trioctylamine (CAS No. 1116-76-3) and tridecylamine (CAS No. 1070-01-5).

Restrictions

Australian

The chemicals in this group (under the generic term amines) may be listed in the *Poisons Standard* (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP 2014)) in Schedule 5 as follows:

'AMINES for use as curing agents for epoxy resins except when separately specified in these Schedules'.

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.

It is noted that use as curing agents for epoxy resins has not been reported for these chemicals.

International

Tridodecylamine (CAS No. 102-87-4), is listed on the following (Galleria Chemica):

EU Cosmetics Regulation 1223/2009 Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down.

Trialkylamines, trialkanolamines and their salts:

- 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.

New Zealand Cosmetic Products Group Standard—Schedule 5: Components cosmetic products must not contain except subject to the restrictions and conditions laid down (Restrictions identical to entry under EU Cosmetics Regulation 1223/2009 Annex III).

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

- For the chemical (CAS No. 68814-95-9), a Temporary Emergency Exposure Limit (TEEL) of up to 1100 (TEEL-3) mg/m^3 has been stated by the US Department of Energy (DOE).
- For the chemicals (CAS Nos. 1116-76-3, 102-87-4) a TEEL of up to 400 (TEEL-3) mg/m^3 has been stated by the US DOE.
- For the chemicals (CAS Nos. 1116-76-3, 1070-01-5, 102-87-4), an occupational exposure limit (OEL) (TWA 1 mg/m^3) in Latvia and 0.14 mg/m^3 in the USA.

Health Hazard Information

Data for the chemicals trioctylamine (CAS No. 1116-76-3) and tri-C8-10-alkyl amines (CAS No. 68814-95-9) have been used to infer effects for tridodecylamine (CAS No. 102-87-4) and tridecylamine (CAS No. 1070-01-5) in the absence of specific data, according to the principles of 'read-across' (OECD 2014).

Acute Toxicity

Oral

The chemicals have low acute toxicity based on a result from an animal test following oral exposure. The median lethal dose (LD50) in Wistar rats for trioctylamine (CAS No 1116-76-3) is >2000 mg/kg bw (REACH).

Trioctylamine (CAS No. 1116-76-3) had low acute toxicity by the oral route in Wistar rats in a test performed in accordance with OECD Test Guideline (TG) 401, with a reported LD50 > 2000 mg/kg bw for both sexes. Observed sub-lethal effects included dyspnoea, apathy and poor general state (days 5 to 6), and spastic gait and piloerection (days 5 to7).

Dermal

The chemicals have low acute toxicity based on a result from an animal test following dermal exposure. The LD50 in rats for tri-C8-10-alkylamines (CAS No. 68814-95-9) is >5000 mg/kg bw (REACH).

Tri-C8-10-alkylamines (CAS No. 68814-95-9) had low acute toxicity by the dermal route in Wistar rats in a test performed in accordance with OECD TG 402, with a reported LD50 of >5000 mg/kg bw for both sexes. There were no observed systemic sub-lethal effects reported.

Local effects were reported, including well-defined to severe erythema (grade 2 to 4), very slight to severe oedema (grade 1 to 4), and encrustations. These effects were noted beyond the application site.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

The chemicals in this group are skin irritants. The available data warrant hazard classification.

Trioctylamine (CAS No. 1116-76-3) was applied to intact rabbit skin in accordance with OECD TG 404 and produced severe erythema and oedema after 24 hours (REACH). After 15 days, oedema was fully reversible in all animals and erythema was fully reversible in 2/3 animals. Additionally, there was scaling beyond the area of application in 2/3 animals.

Eye Irritation

The chemicals in this group are eye irritants. While the available data do not meet classification criteria under the Approved Criteria for Classifying Hazardous Substances (Safe Work Australia), the data meet classification criteria under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS, 2009).

Trioctylamine (CAS No. 1116-76-3) was reported to irritate the eyes when tested according to OECD TG 405 (REACH). The average scores for cornea, iris, conjunctivae (redness), conjunctivae (chemosis) were given as 0/0/2/0 respectively. The effects were reversible within 8 days after application. Additionally, loss of hair at the margins of the eyelids was observed.

Sensitisation

Skin Sensitisation

The negative results observed for the chemical in a Buehler test support a conclusion that the chemicals in this group are not skin sensitisers (REACH). However, the data further support the classification of the chemicals as irritating to the skin.

Tri-C8-10-alkylamines (CAS No. 68814-95-9) was not found to induce dermal sensitisation in Dunkin Hartley guinea pigs when tested according to OECD TG 406. The chemical was not a skin sensitiser after application in challenge phases at a concentration of 50 % or 10 %. The induction period included 3 topical applications with tri-C8-10-alkylamines at 100 % concentration (inductions 1 and 2) and 75 % concentration in liquid paraffin (induction No.3). In the treatment group (50 % concentration in liquid paraffin), slight to moderate oedema in 65, 55 and 50 % of the animals at 24, 48 and 72 hours respectively was reported after the challenge phase, on the treated area. In the control group, slight oedema in 70, 60 and 60 % of the animals at 24, 48 and 72 hours respectively was reported after the challenge phase, on the treated area. A new challenge

was performed with the chemical diluted at 10% in liquid paraffin, after a rest period of 6 days. In the treatment group (10% concentration), moderate erythema in 20% and 30% of the animals at 48 and 72 hours respectively was reported. In the control group (for the 10% challenge), moderate erythema in 30% of the animals at 48 and 72 hours was reported. However, the reactions in the test groups did not exceed the most severe reactions reported in the control groups and, therefore, the effects were not attributed to skin sensitisation.

Repeated Dose Toxicity

Oral

There are data available from one well-conducted subchronic study combined with a reproduction/developmental test, although it is recognised that the quality of this evidence is less reliable than that obtained through full studies (GHS 2009, part 3). The chemicals in this group may cause damage to health from repeated oral exposure, based on the cardiac observations.

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in Wistar rats, conducted in accordance with OECD TG 422, tri-C8-10-octylamines (CAS No. 68814-95-9) was administered at doses of 0, 50, 150, or 400 mg/kg bw/day by gavage (REACH). Males were treated for 43 days while females were treated from the beginning of the study until day 4 of lactation.

Intermittent occurrence of reddish nasal secretion was reported in two males in the high dose group. Bedding found in the mouth and salivation during days 5 to 7 of gestation were reported in one female in the high dose group. These effects may have been due to oral discomfort associated with treatment with the chemical.

There were statistically significant reductions in food consumption and body weight gain in males in the high dose group compared with controls during part of the pre-pairing period (days 4–8). The reduction was less marked during the end of the pre-pairing period. Reduced body weight gain similar to males was reported in females in the high dose group when compared with controls but did not reach statistical significance. The study authors reported the transient reduction in food consumption to be not adverse.

In males in the high dose group, there was a statistically significant increase (1.8-fold increase) in the number of neutrophils compared with controls, and a decrease in the percentage of lymphocytes. Additionally, the haemoglobin and haematocrit values were statistically significantly lower than controls, but close to historical control data. Statistically significant decreases in mean corpuscular haemoglobin and basophil levels were within the range of historical controls. In females, all values from haematology examinations were with historical control values.

In both sexes in the high dose group, there were higher concentrations of aspartate aminotransferase (not statistically significantly different), of alanine aminotransferase (males only) and of alkaline phosphatase. In one male, a pale discoloured liver was reported during necropsy. Other statistically significant differences (creatinine, potassium, chloride, protein and albumin) were within the range of the historical controls.

There were no significant effects on organ weights reported except for the testes and epididymides of males (see **Reproductive/Developmental** section).

In the majority of male and female rats at all doses tested, in the heart, a minimal to moderate multifocal dose-dependent cardiomyopathy (myocardial necrosis and/or degeneration with mononuclear inflammatory infiltration, and often accompanied by fibrosis/fibroplasia) was reported (REACH). At all doses tested, minimal to moderate foamy macrophage accumulation was observed in the lungs. A higher incidence and severity of these effects was reported in males compared with females.

Based on the effects in the heart, a reported LOAEL (lowest observed adverse effect level) of 50 mg/kg bw/day was determined for systemic toxicity.

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

The chemicals in this group are not expected to be genotoxic based on negative studies reported in REACH, in several in vitro (bacterial gene mutation, mammalian cell micronucleus, HPRT gene mutation) tests for gene mutation and clastogenicity (REACH).

For trioctylamine (CAS No. 1116-76-3), negative results were reported in bacterial reverse mutation tests for mutagenicity to *Salmonella typhimurium* (strains included TA 98, TA 100, TA 1535, TA 1537 and TA 153) with and without metabolic activation.

For tri-C8-10-alkylamines (CAS No. 68814-95-9), negative results were reported in Chinese hamster lung fibroblasts (V79) in accordance with OECD TG 487, with and without metabolic activation. Ethanol was used as the vehicle due to poor solubility of the chemical, which precipitated at higher concentrations. Negative results were also reported in Chinese hamster ovary cells in accordance with OECD TG 476, with and without metabolic activation. The chemical was cytoxic to the cells at the highest concentration tested (100 µg/mL).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

There are data available from one well-conducted subchronic study combined with a reproduction/develpomental test, although it is recognised that the quality of this evidence is less reliable than that obtained through full studies (GHS 2009, part 3). The chemicals in this group may cause damage to fertility from repeated oral exposure. At all dosages in the study, developmental toxicity occurred together with other toxic effects in maternal rats. Based on the data available, non-specific mechanisms on maternal toxicity cannot be ruled out.

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in Wistar rats (see **Repeated Dose Toxicity** section), for tri-C8-10-octylamines (CAS No. 68814-95-9), adverse effects to reproductive parameters were reported in addition to the systemic effects (REACH).

There were no differences in mean precoital time, fertility index and conception rate at any dose level. In the mid and high dose groups, no females gave birth. In these groups, there was a post implantation loss of 100 %, and all pregnant females had either only implantation sites or only embryonic resorptions. In the low dose group, there was a higher mean incidence of post-implantation loss.

In males in the mid- and high-dose groups, testes were flaccid and/or reduced in size. In males in the high dose group, statistically significant reductions in testicular and epididymal weights were reported. In the mid- and high-dose groups, a minimal to moderate increase in the formation of the residual bodies of abnormal shape and size was reported in the testes. In the high-dose group, exfoliated residual bodies (cell debri) were reported in the epididymides.

In the low dose group, there were no statistically significant differences in mean number of pups at first litter check, sex ratio, pup weight or pup weight gain. At necropsy of pups, there were no abnormal findings.

A LOAEL of 50 mg/kg bw/day, based on the higher mean incidence of post-implantation loss, was determined for reproductive and developmental toxicity.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (reproductive toxicity and cardiomyopathy). The chemicals can also cause skin and eye irritation.

Public Risk Characterisation

Domestic use of the chemicals in this group has not been identified. The chemicals are currently listed on Schedule 5 of the *Poisons Standard*. The current controls are considered adequate to minimise the risk to public health posed by potential domestic products containing the chemicals.

Although use in cosmetic products in Australia or overseas is not known, tridodecylamine (CAS No. 102-87-4) is listed as having a cosmetic function as an antistatic agent. In such cosmetic formulations, the chemicals are expected to be used at low concentrations and exist as various salts. Therefore, the chemicals are not considered to pose an unreasonable risk to public health.

The European Union has restricted the use of tridodecylamine (CAS No. 102-87-4) in cosmetics.

Occupational Risk Characterisation

Given the critical systemic long-term and local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular 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 Hazardous Substances Information System (HSIS) (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

Assessment of these chemicals are considered to be sufficient, provided that 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 state or territory.

Regulatory Control

Public Health

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2014).

Work Health and Safety

The chemicals are 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.

In the absence of specific data on all of the chemicals, data have been 'read across' according to OECD principles (OECD 2014), from the chemicals in this group for which data was available. Should empirical data become available indicating that a lower (or higher) classification is appropriate for these chemicals, this may be used to amend the default classification.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Irritating to skin (Xi; R38)	Causes serious eye irritation - Cat. 2A (H319) Causes skin irritation - Cat. 2 (H315)
Repeat Dose Toxicity	Harmful: Danger of serious damage to health by prolonged exposure if swallowed (Xn; R48/22)	May cause damage to organs through prolonged or repeated exposure through the oral route - Cat. 2 (H373)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of impaired fertility (Xn; R62)	Suspected of damaging fertility - Cat. 2 (H361f)

[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 chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

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

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the effect on the worker's health;
- 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.

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

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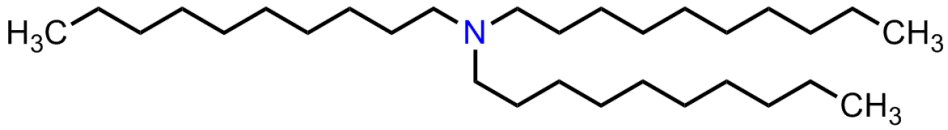
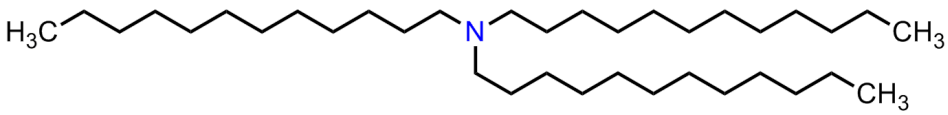
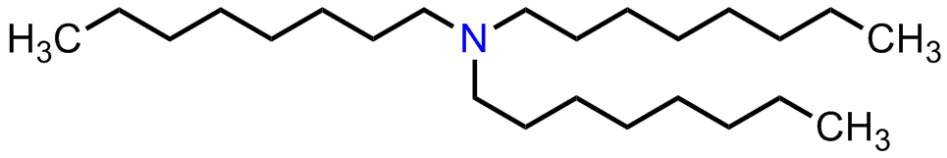
Chemical Identities

Chemical Name in the Inventory and Synonyms	**1-Decanamine, N,N-didecyl-** tris(decyl)amine N,N,N-tridecylamine tri-n-decylamine tridecylamine TDA
CAS Number	1070-01-5
Structural Formula	
Molecular Formula	C30H63N
Molecular Weight	437.84

Chemical Name in the Inventory and Synonyms	**1-Dodecanamine, N,N-didodecyl-** tridodecylamine tri-n-dodecylamine trilaurylamine tris(dodecyl)amine TDA
CAS Number	102-87-4
Structural Formula	
Molecular Formula	C36H75N
Molecular Weight	521.99

Chemical Name in the Inventory and Synonyms	**1-Octanamine, N,N-dioctyl-** tri-n-caprylylamine trioctylamine N,N,N-trioctylamine tri-n-octylamine
CAS Number	1116-76-3

Structural Formula	
Molecular Formula	C24H51N
Molecular Weight	353.67

Chemical Name in the Inventory and Synonyms	**Amines, tri-C8-10-alkyl** tri-C8-10-alkylamines
CAS Number	68814-95-9
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	Unspecified

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