# Tertiary aliphatic (C12-22) and fatty amines: Human health tier II assessment

#### 10 March 2017

- Chemicals in this assessment
- Preface
- Grouping Rationale
- Import, Manufacture and Use
- Restrictions
- Existing Worker Health and Safety Controls
- Health Hazard Information
- Risk Characterisation
- NICNAS Recommendation
- References

## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1-Hexadecanamine, N,N-dimethyl-	112-69-6
1-Tetradecanamine, N,N-dimethyl-	112-75-4
1-Dodecanamine, N,N-dimethyl-	112-18-5
1-Octadecanamine, N,N-dimethyl-	124-28-7
9-Octadecen-1-amine, N,N-dimethyl-, (Z)-	14727-68-5
1-Docosanamine, N,N-dimethyl-	21542-96-1
Amines, dimethylsoya alkyl	61788-91-8
Amines, coco alkyldimethyl	61788-93-0
Amines, (hydrogenated tallow alkyl)dimethyl	61788-95-2
Amines, C12-16-alkyldimethyl-	68439-70-3



Chemical Name in the Inventory	CAS Number
Amines, C10-16-alkyldimethyl	67700-98-5
Amines, C14-18-alkyldimethyl	68037-93-4
Amines, C12-18-alkyldimethyl	68391-04-8
Amines, C14-18 and C16-18-unsaturated alkyl, dimethyl	68391-07-1
Amines, dimethyl tallow alkyl	68814-69-7
Amines, C12-14-alkyldimethyl	84649-84-3
Amines, C18-22-alkyldimethyl	124046-42-0
Amines, C18-22-unsaturated alkyldimethyl	124046-43-1

# 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

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ACRONYMS & ABBREVIATIONS

# **Grouping Rationale**

The chemicals in this group are structurally related tertiary amines with a linear aliphatic chain and are N,N-dimethyl substituted.

The chemicals in this group can have an alkyl chain between 10 and 22 carbon atoms. Some of the chemicals are derived from fatty acids and are comprised of a mixture of alkyl amines where the carbon chain length varies between 10 and 22 carbon atoms (even numbers only). The individual components may also have unsaturation of the alkyl chain.

Commercially, high purity alkyl amines are isolated by fractional distillation of fatty alkyl amine products. Alkyl amines are derived from natural sources and converted through catalytic hydrogenation of nitrile intermediates. The carbon chain distribution of the naturally derived chemicals will vary depending on the method of production and the source of the precursor chemicals. Data regarding the typical composition of the chemicals in this group are limited to the following fatty amines:

- C12-16-alkyldimethyl amines (CAS No. 68439-70-3) (<C12: <2 %, C12: 63–75 %, C14: 24–30 %, C16: 5 %, C18: <0.5 %); and
- coco alkyldimethyl amines (CAS No. 61788-93-0) (<C12: 6-22 %, C12: 45–55 %, C14: 14–24 %, C16: 5–13 %, C18: 4–12 %).</li>

An increasing percentage of unsaturation of the alkyl chains decreases the melting point of the chemical while the reactivity is expected to increase. The tertiary amine functional group is strongly basic and is the most relevant functional group for consideration of the toxicity of any endpoint.

The chemicals in this group have average molecular weights between 213 and 354 Da. Although the molecular weight of the chemicals in this group is below 500 Da, high dermal absorption is not expected due to the log Kow > 7.

# Import, Manufacture and Use

## Australian

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

- dodecyldimethylamine (CAS No. 112-18-5),
- tetradecyldimethylamine (CAS No. 112-75-4), and
- C12-16-alkyldimethyl amines (CAS No. 68439-70-3)

have reported domestic use in cleaning/washing agents, and additives.

No specific Australian use, import, or manufacturing information has been identified for other members of this group.

16/04/2020

The total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was between 100 and 1000 tonnes for the above stated three chemicals (CAS Nos 112-18-5, 112-75-4, 68439-70-3).

## International

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

The chemicals in this group are included in the CosIng database and US Personal Care Products Council INCI directory with the identified functions of an antistatic and/or emulsifying agent. There are documented uses (domestic cleaning products) for C12-16-alkyldimethyl amines (CAS No. 68439-70-3) and C12-18-alkyldimethyl amines (CAS No. 68391-04-8) in the United States of America (USA). The chemical octadecyldimethylamine (CAS No. 124-28-7) has a moderate reported use frequency of (41 products) in cosmetic products (ed. Bailey 2011).

Dodecyldimethylamine (CAS No. 112-18-5), tetradecyldimethylamine (CAS No. 112-75-4) and coco alkyl dimethyl amine (CAS No. 61788-93-0) have reported domestic use as surfactants, and cleaning and washing agents. Coco alkyldimethyl amine (CAS No. 61788-93-0) also has reported domestic use as a corrosion inhibitor.

Coco alkyldimethyl amine (CAS No. 61788-93-0) and C12-18-alkyldimethyl amines (CAS No. 68391-04-8) have reported commercial use as lubricants and additives.

Some of the chemicals in this group have reported site-limited use as intermediates (REACH).

There is no reported use information available for C14-18-alkyldimethyl amines (CAS No. 68037-93-4), C12-14-alkyldimethyl amines (CAS No. 84649-84-3), N,N-dimethyl-9-octadecen-1-amine, (Z)- (CAS No. 14727-68-5), C18-22-unsaturated alkyldimethyl amines (CAS No. 124046-43-1), N,N-dimethyl-, (Z)-and C18-22-alkyldimethyl amines (CAS No. 124046-42-0).

## Restrictions

## Australian

The chemicals in this group (under the generic term amines) are listed in the *Poisons Standard*, *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP, 2013) 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.

## International

The chemicals in this group, with the exception of C12-16-alkyldimethyl amines (CAS No. 68439-70-3), are subject to restrictions on the following:

The 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.

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment\_id=1049

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 in this group are not listed on the Hazardous Chemicals Information System (HCIS) (Safe Work Australia).

## **Exposure Standards**

#### Australian

No specific exposure standards are available for the chemicals in this group.

#### International

The following exposure standards are identified (Galleria Chemica):

dodecyldimethylamine (CAS No. 112-18-5), hexadecyldimethylamine (CAS No. 112-69-6), tetradecyldimethylamine (CAS No. 112-75-4) and octadecyldimethylamine (CAS No. 124-28-7) have an occupational exposure limit (OELV, 8 hour) of 1 mg/m<sup>3</sup> in Latvia and a new chemical exposure limit (NCEL) of 0.14 mg/m<sup>3</sup> in the USA.

## **Health Hazard Information**

#### **Acute Toxicity**

#### Oral

The chemicals in this group are expected to have moderate acute toxicity in animal tests following oral exposure. The available data (median lethal dose—LD50—624 to 2116 mg/kg bw) warrant classification of the chemicals in this group (refer to **Recommendation** section).

In two studies conducted in accordance with OECD Test Guideline (TG) 401 reported in REACH, dodecyldimethylamine (CAS No. 112-18-5) had moderate toxicity in acute oral tests. The range of LD50 values in rats was found to be between 1000 and 1250 mg/kg bw. In one study, sub-lethal effects were observed at all doses, including lethargy, diarrhoea, piloerection, and

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment\_id=1049

#### IMAP Group Assessment Report

changes in motor activity. In the second study, observed sub-lethal effects included bloody crusted eyelids and mouths, laboured breathing, and diarrhoea. Heart, lung and gastrointestinal abnormalities were observed in animals that died during the studies.

In 13 studies summarised in US EPA (2010), tetradecyldimethylamine (CAS No. 112-75-4), hexadecyldimethylamine (CAS No. 112-69-6), octadecyldimethylamine (CAS No. 124-28-7), (hydrogenated tallow alkyl)dimethyl amines (CAS No. 61788-95-2) and soya alkyldimethyl amines (CAS No. 61788-91-8) had moderate toxicity in acute oral tests. The LD50 values in rats were in the range of 624 to 2116 mg/kg bw. The number of mortalities per dose were reported, although sub-lethal effects were not reported. Further study details were also available in TSCATS (a) for dodecyldimethylamine (CAS No. 112-18-5), tetradecyldimethylamine (CAS No. 112-75-4), hexadecyldimethylamine (CAS No. 112-69-6) and octadecyldimethylamine (CAS No. 124-28-7). The observed sub-lethal effects common to all studies included lethargy, piloerection, ptosis, diarrhoea and ataxia.

In six study summaries performed to OECD TG 401 reported in ACToR (a), coco alkyldimethyl amine (CAS No. 61788-93-0) was reported to have moderate acute toxicity following oral exposure. The range of LD50 values in rats was between >1000 and 1500 mg/kg bw.

#### Dermal

The chemicals in this group have low acute toxicity in animal tests following dermal exposure. The LD50 in rats is greater than 2000 mg/kg bw.

In ten studies summarised in US EPA (2010), tetradecyldimethylamine (CAS No. 112-75-4), hexadecyldimethylamine (CAS No. 112-69-6), octadecyldimethylamine (CAS No. 124-28-7) and soya alkyldimethyl amines (CAS No. 61788-91-8) were reported to have moderate toxicity in acute dermal tests. The LD50 values in rats were in the range ~2400 to ~3432 mg/kg bw. The number of mortalities per dose were reported, although sub-lethal effects were not reported. Further study details were also reported in TSCATS (a) for dodecyldimethylamine (CAS No. 112-18-5), tetradecyldimethylamine (CAS No. 112-75-4),

hexadecyldimethylamine (CAS No. 112-69-6) and octadecyldimethylamine (CAS No. 124-28-7). The observed sub-lethal effects common to all studies included lethargy, ptosis, diarrhoea, yellow nasal discharge, and ataxia.

Inhalation

No data are available.

Due to the corrosive properties reported for some of the chemicals in this group, acute inhalation testing is not required unless information becomes available to indicate that systemic effects may occur at non-corrosive (low level) concentrations.

## **Corrosion / Irritation**

## Corrosivity

The chemicals in this group are considered to be corrosive. While the severity of these effects varied, information was sufficiently available across the group to support the need for classification (refer to **Recommendation** section). Corrosive chemicals are also considered to cause irreversible effects on the eyes and respiratory irritation; the available eye irritation data for the chemicals supports this finding.

#### Effects on the skin:

In three studies reported (REACH), performed in accordance with OECD TG 404, undiluted dodecyldimethylamine (CAS No. 112-18-5) was corrosive to rabbit skin in two studies and an irritant in one study following occlusive exposure for either 3 minutes or 4 hours. In the studies where there was also a test with three minutes' exposure to the chemical, no animals tested had a score of 4 for erythema or eschar between 30 and 60 minutes after exposure. Therefore, the chemicals do not meet the criteria for HCIS classification for Skin Corrosion category 1A 'Causes severe skin burns and eye damage'.

#### IMAP Group Assessment Report

In studies performed similar to OECD TG 404 (TSCATS a), undiluted dodecyldimethylamine (CAS No. 112-18-5) and tetradecyldimethylamine (CAS No. 112-75-4) were severely irritating, and hexadecyldimethylamine (CAS No. 112-69-6) and octadecyldimethylamine (CAS No. 124-28-7) were corrosive to the skin of rabbits. There were a wide variation in scores for erythema and oedema between animals and for each chemical, although the severity of erythema increased over time for all chemicals.

In a summary report in the International Uniform Chemical Information Database (IUCLID) (2000 a), undiluted (hydrogenated tallow alkyl)dimethyl amine (CAS No. 61788-95-2) was corrosive to the skin of rabbits in a study performed in accordance with OECD TG 404. In two summaries reported in IUCLID (2000 b), undiluted C12-14-alkyldimethyl amines (CAS No. 84649-84-3) was corrosive to the skin of rabbits performed in accordance with OECD TG 404 and the Draize Test.

In five summary reports in ACToR (a), coco alkyldimethyl amines (CAS No. 61788-93-0) was corrosive to the skin of rabbits in studies performed in accordance with OECD TG 404. In a study summary report in ACToR (b), the analogue C10-16alkyldimethyl amines (CAS No. 67700-98-5) was corrosive to the skin of rabbits at concentrations of 3 %, 30 %, and when undiluted.

#### Effects on the eye:

In an EU REACH study, C12-16-alkyldimethyl amines (CAS No. 68439-70-3) was reported to be severely irritating to the eyes of a rabbit when tested according to OECD TG 405. The average scores for corneal opacity, iritis, conjunctival redness and conjunctival oedema (chemosis) were given as 0.66, 1.0, 2.33 and 2.0 respectively. The effects in the conjunctivae were not reversible within 21 days. Necrosis and ulceration of the conjuntivae could not be assessed from 72 hours to the end of the study due to eye swelling. Peri-orbital exfoliation, hair loss and sloughing was observed from day 15 onwards.

In studies (similar to the Draize test) reported in TSCATS (a), dodecyldimethylamine (CAS No. 112-18-5), hexadecyldimethylamine (CAS No. 112-69-6), tetradecyldimethylamine (CAS No. 112-75-4) and octadecyldimethylamine (CAS No. 124-28-7) were severely irritating to the eyes of rabbits (6 per chemical). The average scores for corneal opacity, iritis, conjunctival redness and conjunctival oedema (chemosis) were 0, 0, 3.1 and 1.1 respectively. Corrosive effects (blistering on the eyelids) were observed from day one for all rabbits exposed to octadecyldimethylamine (CAS No. 124-28-7). As the test was discontinued after three days, the reversibility of the effects could not be evaluated.

#### Observation in humans

Although limited data are available, the chemicals in this group are not expected to be irritating to the skin of humans at low concentrations.

In two cumulative irritation studies reported with octadecyldimethylamine (CAS No. 112-18-5), the chemical was tested at 0.5 % concentration in one study and up to 1 % concentration (including as formulated hair spray and in denatured alcohol) in the second study. The studies evaluated 198 and 215 subjects, respectively. The details of the dose or unit area and formulation were not reported in either study. While the chemical was not an irritant at 0.5 % concentration, barely perceptible erythema was observed at 1 % concentration (CIR 2009).

## Sensitisation

#### Skin Sensitisation

Limited data are available for one chemical in the group and an analogue chemical C10-16-alkyldimethyl amines (CAS No. 67700-98-5). The available data do not warrant hazard classification.

The chemicals C10-16-alkyldimethyl amines (CAS No. 67700-98-5) and tallow alkyldimethyl amines (CAS No. 68814-69-7) were reported to not be skin sensitisers at 25 % concentration in a study similar to the guinea pig maximisation test, although no other details of the study were reported (ACToR b).

#### Observation in humans

Limited data are available for the chemicals in this group.

The previously reported cumulative irritation studies for octadecyldimethylamine (CAS No. 112-18-5) (see **Irritation: Observation in humans**) were also designed to evaluate contact sensitisation. The chemical was reported not to be a skin sensitiser in humans (CIR 2009).

## **Repeated Dose Toxicity**

Oral

Although the available data are limited, the chemicals in this group are not considered to cause serious damage to health from repeated oral exposure.

In a 28-day study performed according to OECD TG 407, dodecyldimethylamine (CAS No. 112-18-5) was administered (gavage) to Sprague Dawley (SD) rats at dosages of 0, 50, 150 or 300 mg/kg bw/day. As no adverse clinical signs were observed at the lowest dose, a no observed effect level (NOEL) of 50 mg/kg bw/day was reported. At doses of 150 mg/kg bw/day and higher, signs of slight toxicity (rubbing of snouts in bedding material) was observed after dosing, although this behaviour was of short duration (about 5 min) (REACH).

#### Dermal

No data are available.

Inhalation

No data are available.

## Genotoxicity

Although the available data are limited for the chemicals in this group, the available information indicates that the chemicals in this group are not considered to have mutagenic or genotoxic potential.

In studies reported in US EPA (2010), negative results were reported in bacterial reverse mutation tests with *Salmonella typhimurium* (strains TA98, TA100) for tetradecyldimethylamine (CAS No. 112-75-4), hexadecyldimethylamine (CAS No. 112-69-6), and octadecyldimethylamine (CAS No. 124-28-7). However, the guidelines require at least five different strains as each strain identifies a different type of mutation. Cytoxicity was observed at the highest dose (50 µg/plate).

In another bacterial reverse mutation test according to OECD TG 471, the chemical identity was inconsistently reported, either as dodecyldimethylamine (CAS No. 112-18-5) (REACH) or a commercial mixture containing C12-14 alkyl dimethylamines (CAS No. 84649-84-3) (US EPA 2010). This chemical was not mutagenic in bacterial reverse mutation tests to *S. typhimurium* (strains TA98, TA100, TA1535, TA1537, and TA1538) and *Escherichia coli* (WP2uvrA) up to a concentration of 500 µg/plate. Cytotoxicity was not reported.

In a mouse micronucleus test, the chemical identity was inconsistently reported, either as dodecyldimethylamine (CAS No. 112-18-5) (REACH; CIR 2009) or a commercial mixture containing C12-14-alkyldimethyl amines (CAS No. 84649-84-3) (US EPA 2010). This chemical did not induce chromosomal damage in the mouse micronucleus test after an acute oral dose up to 1200 mg/kg bw. In the high dose group, six out of ten mice died prematurely, indicating that the chemical was tested to the upper limit of toxicity. The animals were replaced and the new animals survived to the end of the study.

## Carcinogenicity

Limited data are available for the chemicals in this group.

In a non-guideline study reported in CIR (2009), dodecyldimethylamine (CAS No. 112-18-5) was orally fed to SD rats in drinking water at 0.18 % concentration for 80 weeks (mg/kg bw equivalent not reported). No significant differences in survival, feed consumption or weight gain, or increase in neoplasms between the treated and control groups were reported. An additional exposure group where the chemical was supplemented with 0.2 % sodium nitrate showed significant increases in the incidence of urinary bladder and forestomach tumours. This supports the current EU restriction of the chemicals in this group from use with nitrosating systems and the requirement that they should be used in nitrite-free cosmetic formulations.

### **Reproductive and Developmental Toxicity**

Although the available data are limited, chemicals in this group are not considered to have specific reproductive or developmental toxicity. Any reproductive and developmental effects were only observed secondary to maternal toxicity.

In a reproductive/developmental toxicity screening study conducted in accordance with OECD TG 421, SD rats (10/sex/group) were exposed to dodecyldimethylamine (CAS No. 112-18-5) at dosages of 0, 50, 150, 300 or 450 mg/kg bw/day by gavage. Males were treated for 28 days while females were treated from the beginning of the study until day three of lactation. The highest dose group was discontinued on day four due to early unscheduled deaths and the poor health of surviving animals. In the 300 mg/kg bw/day group, one male and six females died during the study, with only one pup born in the group. In the 150 mg/kg bw/day group, there were significant increases in the number of stillbirths, decreases in male pup birthweight, increases in the mean post-implantation loss and decreases in the mean viability index. In the 50 mg/kg bw/day dose group there were no changes in clinical signs, body weight gain or in feed consumption. There were also no reported adverse effects for reproductive parameters (number of corpora lutea, implantation sites, viable foetuses, changes in body weight or sex-ratio of the pups). Based on the results, a reported NOEL of 50 mg/kg bw/day was determined for reproductive and developmental toxicity (CIR 2009; REACH).

## **Risk Characterisation**

## **Critical Health Effects**

The critical health effect for risk characterisation of these chemicals is local corrosivity. The chemicals also have moderate acute oral toxicity.

#### **Public Risk Characterisation**

The chemicals are used only as antistatic and/or emulsifying agents in cosmetics (CosIng) and therefore public exposure to high concentrations of the chemical is not expected through cosmetic uses. The general public may be exposed to the chemicals via the dermal and/or inhalation routes when using domestic products containing these chemicals. However, based on limited USA information derived from the National Library of Medicine (NLM) Household Products Database, the concentration of these chemicals in these products is not considered to be sufficiently high to cause corrosive effects. Therefore, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

The EU has restricted the use of these chemicals in cosmetics. Currently, there are no restrictions on using these chemicals in Australia.

### **Occupational Risk Characterisation**

During product formulation, dermal,ocular and inhalation exposure of workers to these chemicals can occur, particularly where manual or open processes are used. These may 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 health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemicals 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 appropriate controls.

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

## **NICNAS Recommendation**

Assessment of the chemicals is 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).

#### 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.

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

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Not Applicable	May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335) Causes severe skin burns and eye damage - Cat. 1B (H314)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> 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 instruction on the label.

## Advice for industry

## **Control measures**

Control measures to minimise the risk from dermal, ocular and inhalation 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 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 chemicals has not been undertaken as part of this assessment.

# References

Aggregated Computational Toxicology Resource (ACToR). Cocoalkyldimethylamines (CAS No. 61788-93-0). Accessed June 2014 at http://actor.epa.gov/actor/GenericChemical?casrn=61788-93-0

Bailey, JE (ed.) 2011, Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS), 1st Edition, Personal Care Products Council, Washington, D.C.

Cosmetic Ingredient Review 2009. Dimethyl Stearamine and Related Tertiary Aliphatic Amines as Used in Cosmetics. Accessed May 2014 at http://www.cir-safety.org/ingredients

Galleria Chemica. Accessed February 2017 at http://jr.chemwatch.net/galleria/

Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Accessed at http://www.unece.org/trans/danger/publi/ghs/ghs\_rev03/03files\_e.html

OECD (2014). Guidance on Grouping of Chemicals, Second Edition. Environment Directorate. Joint meeting of the Chemicals Committee and the Working party on Chemicals, Pesticides and Biotechnology. Series on Testing& Assessment No. 194. Accessed April 2014 at http://search.oecd.org/officialdocuments/displaydocumentpdf/? cote=env/jm/mono(2014)4&doclanguage=en

Registration, Evaluation, Authorisation and Restriciton of Chemicals (REACH) Dossier. N,N-Dimethyl-1-dodecanamine (CAS No. 112-18-5). Accessed June 2014 at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Safe Work Australia. Hazardous Chemicals Information System (HCIS). Accessed February 2017 at http://hcis.safeworkaustralia.gov.au/HazardousChemical

The International Uniform Chemical Information Database (IUCLID) 2000. Dataset on substance ID 61788-95-2. European Commission 18 February 2000. Accessed June 2013 at http://esis.jrc.ec.europa.eu/doc/IUCLID/data\_sheets/61788952.pdf

The International Uniform Chemical Information Database (IUCLID) 2000. Dataset on substance ID 84649-84-3. European Commission 19 February 2000. Accessed June 2013 at http://esis.jrc.ec.europa.eu/doc/IUCLID/data\_sheets/94649843.pdf

The Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) 2013. Accessed April 2014 at http://www.comlaw.gov.au/Details/F2013L01607/Download

Toxic Substance Control Act Test Submission (TOSCATS a). Document Control Number 84940000191, Submitting Company: Ethyl Corporation. Accessed June 2014 at http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearch?OpenForm

Toxic Substance Control Act Test Submission (TOSCATS b). Document Control Number 84940000235, Submitting Company: Proctor& Gamble. Accessed June 2014 at http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearch?OpenForm

US Environmental Protection Agency (US EPA) (2010). Screening-Level Hazard Characterization: Fatty Nitrogen Derived Amines category. Accessed June 2014 at

http://www.epa.gov/chemrtk/hpvis/hazchar/Category\_FND%20Amines\_September\_2010.pdf

Last Update 10 March 2017

## **Chemical Identities**

Chemical Name in the Inventory and Synonyms	<b>1-Hexadecanamine, N,N-dimethyl-</b> dimethylcetylamine hexadecyldimethylamine N,N-dimethylhexadecylamine
CAS Number	112-69-6
Structural Formula	$H_3C$ $N$ $CH_3$ $N$ $CH_3$ $CH_3$

Molecular Formula	C18H39N
Molecular Weight	269.51

Chemical Name in the Inventory and Synonyms	<b>1-Tetradecanamine, N,N-dimethyl-</b> N,N-dimethyltetradecylamine tetradecyldimethylamine myristylamine
CAS Number	112-75-4
Structural Formula	$H_3C$ $N$ $CH_3$ $H_3C$ $H_3C$ $H_3$ $CH_3$
Molecular Formula	C16H35N
Molecular Weight	241.46

Chemical Name in the Inventory and Synonyms	<b>1-Dodecanamine, N,N-dimethyl-</b> dodecyldimethylamine lauryl dimethylamine
CAS Number	112-18-5
Structural Formula	$H_3C$ $\sim$ $N$ $CH_3$ $CH_3$ $CH_3$
Molecular Formula	C14H31N
Molecular Weight	213.4

Chemical Name in the Inventory and Synonyms	<b>1-Octadecanamine, N,N-dimethyl-</b> dimethylstearylamine N,N-dimethyloctadecylamine octadecyldimethylamine	

CAS Number	124-28-7
Structural Formula	H <sub>3</sub> C
Molecular Formula	C20H43N
Molecular Weight	297.57

Chemical Name in the Inventory and Synonyms	<b>9-Octadecen-1-amine, N,N-dimethyl-, (Z)-</b> (9-octadecenyl)dimethylamine, (Z)-
CAS Number	14727-68-5
Structural Formula	CH <sub>3</sub> CH <sub>3</sub>
Molecular Formula	C20H41N
Molecular Weight	295.55

Chemical Name in the Inventory and Synonyms	<b>1-Docosanamine, N,N-dimethyl-</b> N,N-dimethyl behenylamine docosyldimethylamine
CAS Number	21542-96-1
Structural Formula	H <sub>3</sub> C
Molecular Formula	C24H51N
Molecular Weight	339.64

Chemical Name in the Inventory and Synonyms	<b>Amines, dimethylsoya alkyl</b> N,N-dimethyl(soybean oil alkyl)amine soya alkyldimethyl amines
CAS Number	61788-91-8
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, coco alkyldimethyl N,N-dimethyl(coconut oil alkyl)amine cocoalkyl dimethyl amines coco alkyldimethyl amine
CAS Number	61788-93-0
Structural Formula	

	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, (hydrogenated tallow alkyl)dimethyl N,N-dimethyl-H-tallow amine (hydrogenated tallow alkyl)dimethyl amine
CAS Number	61788-95-2
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

IMAP Group Assessment Report

Chemical Name in the Inventory and Synonyms	<b>Amines, C12-16-alkyldimethyl-</b> (C12-16) alkyldimethylamine C12-16-alkyldimethyl amines
CAS Number	68439-70-3
Structural Formula	$H_3C$ $H_3C$ $H_3$ $H_3$ $H_3C$ $H_3$
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	<b>Amines, C10-16-alkyldimethyl</b> (C10-16) alkyldimethylamine SDA 150-40-00
CAS Number	67700-98-5
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	227.43

Chemical Name in the Inventory and Synonyms

Amines, C14-18-alkyldimethyl (C14-18) alkyldimethylamine C14-18-alkyldimethyl amines

CAS Number	68037-93-4
Structural Formula	$H_3C$ $H_3C$ $N$ $CH_3$ $H_3C$ $H_3C$ $H_3$ $H_3C$ $H_3$ $CH_3$ $CH_3$
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, C12-18-alkyldimethyl (C12-18) alkyldimethylamine C12-18-alkyldimethyl amines
CAS Number	68391-04-8
Structural Formula	$H_3C$ $H_3C$ $H_3$ $H_3$ $H_3C$ $H_3$ $H_$
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, C14-18 and C16-18-unsaturated alkyl, dimethyl (C14-18) and (C16-18-Unsaturated) alkyldimethylamine
CAS Number	68391-07-1
Structural Formula	

# No Structural

# **Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	267.50

Chemical Name in the Inventory and Synonyms	<b>Amines, dimethyl tallow alkyl</b> N,N-dimethyl-N-(tallow alkyl)amine tallow alkyldimethyl amines
CAS Number	68814-69-7
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the

04/2020 Inventory and Synonyms	IMAP Group Assessment Report C12-14-alkyldimethyl amines
CAS Number	84649-84-3
Structural Formula	$H_3C$ $H_3C$ $H_3$
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, C18-22-alkyldimethyl C18-22-alkyldimethyl amines
CAS Number	124046-42-0
Structural Formula	$H_3C$ $H_3C$ $N_{CH_3}$ $H_3C$ $H_3C$ $H_3$
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Amines, C18-22-unsaturated alkyldimethyl
CAS Number	124046-43-1
Structural Formula	

NO Structural	No	Structural	
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# **Diagram Available**

Molecular Formula	Unspecified
Molecular Weight	

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