Fatty acid amido propyl dimethylamines: Human health tier II assessment

12 December 2019

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
9-Octadecenamide, N-[3-(dimethylamino)propyl]-, (Z)-	109-28-4
Dodecanamide, N-[3-(dimethylamino)propyl]-	3179-80-4
Octadecanamide, N-[3-(dimethylamino)propyl]-	7651-02-7
9-Octadecenamide, N-[3-(dimethylamino)propyl]-12-hydroxy-, [R-(Z)]-	20457-75-4
Hexadecanamide, N-[3-(dimethylamino)propyl]-	39669-97-1
Tetradecanamide, N-[3-(dimethylamino)propyl]-	45267-19-4
Docosanamide, N-[3-(dimethylamino)propyl]-	60270-33-9
Isooctadecanamide, N-[3-(dimethylamino)propyl]-	67799-04-6
Amides, coco, N-[3-(dimethylamino)propyl]	68140-01-2

Chemical Name in the Inventory	CAS Number
Amides, soya, N-[3-(dimethylamino)propyl]	68188-30-7
Amides, tall oil fatty, N-[3-(dimethylamino)propyl]	68650-79-3
Amides, mink oil, N-[3-(dimethylamino)propyl]	68953-11-7
Amides, tallow, hydrogenated, N-[(dimethylamino)propyl]	69013-24-7
Amides, C8-22, N-[3-(dimethylamino)propyl]	84082-43-9

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**

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

Chemicals in this group are fatty acid amidopropyl dimethylamines (amidoamines) and their primary function is to act as antistatic agents in cosmetic products. Given the similar structural and functional properties, these chemicals are expected to have similar toxicological profiles and qualify to be assessed as a group.

Import, Manufacture and Use

Australian

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

Oleamidopropyl dimethylamine (CAS No. 109-28-4) has reported domestic use in adhesives and binding agents, and site-limited use in the manufacture of other chemicals (HVICL, 2006).

International

The following international uses have been identified through Galleria Chemica; the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; 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 US Household Products Database (HPD); and the Organisation for Economic Cooperation and Development (OECD) High Production Volume (HPV) Chemicals Program.

No industrial use information is available for hydrogenated tallow acids, dimethylaminopropylamide (CAS No. 69013-24-7) and amides, C8–22, N-[3-(dimethylamino)propyl] (CAS No. 84082-43-9).

All other chemicals in this group have reported cosmetic uses as antistatic/surfactant agents found in personal care products such as shampoos, conditioners, makeup, moisturisers and various creams (CosIng; INCI).

Stearamidopropyl dimethylamine (CAS No. 7651-02-7) has reported domestic use as a surfactant in various cleaning products (HPD).

Most of these chemicals have reported site-limited uses as intermediates in the synthesis of surfactants and fine chemicals (CIR, 2019; REACHa; REACHb; REACHc; REACHd; REACHe; REACHf).

Myristamidopropyl dimethylamine (CAS No. 45267-19-4) has reported non-industrial use as a biocide in contact lens disinfecting solution (concentration reported to be ~0.0005 %) (CIR, 2019).

Stearamidopropyl dimethylamine has the most reported frequency of uses in cosmetic and personal care products in the USA (assumed to be largely relevant to Australia), with a total of 427 uses (355 rinse-off uses) with maximum concentrations ranging from 0.01–5 % (5 % reported in non-colouring hair conditioners). Behenamidopropyl dimethylamine has the second highest frequency of use, with a total of 53 uses (51 rinse-off uses) with maximum concentrations ranging from 0.3–3 % (3 % reported in non-colouring hair conditioners). Cocamidopropyl dimethylamine has a total frequency of 17 uses (11 rinse-off uses) with maximum concentrations ranging from 0.003–6.5 % (6.5 % reported in skin cleansing products). A few uses were reported for oleamidopropyl dimethylamine (13), isostearamidopropyl dimethylamine (10), lauramidopropyl dimethylamine (2),

palmitamidopropyl dimethylamine (1) and minkamidopropyl dimethylamine (1) with maximum concentrations ranging from 0.0015–1 % (CIR, 2019).

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standard is identified for stearamidopropyl dimethylamine (Galleria Chemica):

Time Weighted Average (TWA): 10 mg/m^3 in Ireland.

Health Hazard Information

Chemicals in this group are fatty acid amidopropyl dimethylamine compounds and their main function is to act as antistatic agents in cosmetic products. These chemicals are manufactured by the amidation of fatty acids with 3,3-dimethylaminopropylamine (DMAPA) under alkaline or acidic conditions. They share an identical core structure containing two primary functional groups, a secondary amide and a tertiary amine, separated by a propyl chain. Different fatty acid chains are attached to the amide functional group. Despite the long fatty acid chain substituents, these chemicals are readily solubilised in water forming cationic ammonium salts. Due to their high polarity, both as free tertiary amines and as ammonium salts, these chemicals are excellent dissipators of triboelectric charges (a type of contact electrification where materials become electrically charged after they are separated) even at low concentrations (e.g., 0.1 % w/w). This property enables these chemicals to be used as antistatic and conditioning agents in cosmetic products. Other uses of the chemicals in this group include functional surfactants, thickeners and bacteriostatic agents (CIR, 2019).

Cocamidopropyl dimethylamine, soyamidopropyl dimethylamine, tallamidopropyl dimethylamine and minkamidopropyl dimethylamine contain various fatty acid chain lengths derived from their corresponding natural products. Lauramidopropyl

dimethylamine is a major component (44–51 %) of cocamidopropyl dimethylamine; and therefore, it is expected to share similar local and systemic toxicological properties (Lal et al., 2003).

Toxicokinetics

No specific information is available on the absorption, distribution, metabolism or excretion of fatty acid amidopropyl dimethylamines. Generally, these chemicals are expected to be taken up via oral route and the majority is expected to be excreted unchanged in faeces. The core structure of these chemicals contains a secondary amide and a tertiary amine. Although nitrosamine content has not been reported, these amide and amine groups can be potentially nitrosated under physiological conditions. Therefore, manufacturers need to take this into consideration when formulating these chemicals so that the formation of nitrosoamines is avoided.

Acute Toxicity

Oral

Based on the available data in rats, lauramidopropyl dimethylamine, stearamidopropyl dimethylamine and cocamidopropyl dimethylamine have moderate toxicity, warranting classification (see **Recommendation** section). Four of the chemicals, oleamidopropyl dimethylamine, ricinoleamidopropyl dimethylamine, behenamidopropyl dimethylamine and tallamidopropyl dimethylamine have low acute oral toxicity.

The reported median lethal doses (LD50) are:

- oleamidopropyl dimethylamine, >2000 mg/kg bw (REACHa);
- lauramidopropyl dimethylamine, 300–1740 mg/kg bw (REACHb);
- stearamidopropyl dimethylamine, 1396 mg/kg bw (REACHc);
- ricinoleamidopropyl dimethylamine, >2000 mg/kg bw (REACHd);
- behenamidopropyl dimethylamine, >2000 mg/kg bw (REACHe);
- cocamidopropyl dimethylamine, 300–2000 mg/kg bw (Galleria Chemica); and
- tallamidopropyl dimethylamine, >2000 mg/kg bw (REACHf).

Dermal

Based on the available data in experimental animals, the chemicals in this group have low acute toxicity following dermal exposure.

The reported dermal LD50 values are:

- oleamidopropyl dimethylamine, >2000 mg/kg bw in rats (REACHa);
- stearamidopropyl dimethylamine, >2000 mg/kg bw in rabbits (REACHc); and
- behenamidopropyl dimethylamine, >2000 mg/kg bw in rabbits (REACHe).

Inhalation

No data are available.

Corrosion / Irritation

Corrosivity

Based on the weight of evidence on the available data, and similar structural profiles and toxicophores, it is anticipated that the chemicals in this group will have similar properties relating to corrosivity. Corrosive chemicals are expected to cause severe eye damage. Therefore, all the chemicals in this group warrant classification for skin corrosion and severe eye damange (see **Recommendation** section).

Dermal

Cocamidopropyl dimethylamine

In an in vivo skin irritation study conducted similarly to OECD Test Guideline (TG) 404, the undiluted chemical was applied to 5 rabbits for 30 minutes exposure. Intense erythema, crust development, necrotic skin alteration and moderate oedema were observed. Under the test conditions, the chemical was considered to be corrosive to skin (Galleria Chemica). No other details of the study are available.

Tallamidopropyl dimethylamine

In an in vivo skin irritation study conducted according to OECD TG 404, 500 mL of the chemical was applied to 2 flanks of a single New Zealand White rabbit (male) under semi-occlusive conditions for an exposure period of 3 minutes and 4 hours, followed by observation up to 24 hours. The observation was terminated on day 2 due to ethical reasons. Cutaneous reactions were observed approximately 1 hour and 24 hours after removal of the dressing. Necrosis was noted at the application site 24 hours after removal of the dressing (day 2). Due to the severity of effects in this animal, no further animals were tested. The chemical was considered to be corrosive to skin under the test conditions (REACHf).

Stearamidopropyl dimethylamine

In an in vivo skin irritation study conducted according to OECD TG 404, 500 mg of the chemical mixed with 0.7 mL of water was applied to the flank of young adult New Zealand White rabbits (n=3, one sex) under semi-occlusive conditions for an exposure period of 4 hours, followed by observation up to 14 days. The average scores at 24, 48 and 72 hours were 1.6, 2.0 and 2.0 for erythema, and 1.0, 1.3 and 1.0 for oedema. All effects were fully reversible within 7 days in one animal and after 14 days in two other animals. Therefore, the chemical was not considered to be irritant to skin under the test conditions (CIR, 2019; REACHc).

Behenamidopropyl dimethylamine

An in vivo skin irritation study was conducted in accordance with OECD TG 404 using a chemical mixture of 50:50 (w/w %) stearamidopropyl dimethylamine and behenamidopropyl dimethylamine. The mixture (500 mg) was applied to adult New Zealand White rabbits (1 male, 2 females) under semi-occlusive conditions for an exposure period of 4 hours, followed by observation up to 10 days. The average scores at 24, 48 and 72 hours were 2.00, 1.67 and 0.00 for erythema respectively, and 0.00, 0.67 and 0.00 for oedema respectively. All effects were fully reversible within 7 days in one animal and after 14 days in the two other animals. Therefore, the chemical was not considered to be irritant to skin under the test conditions (REACHe).

The outcomes of the in vivo studies show more variation than would be expected based on their chemical properties. However, this can be attributed to a physio-chemical difference, with the corrosive substances being liquids and the less irritating substances solids. The better skin contact with the liquids is the assumed reason for the difference. When the chemicals are present in liquid formulations, these differences are not expected to be relevant.

In vitro

The following results were reported for in vitro skin irritation/corrosion studies:

- cocamidopropyl dimethylamine was positive in a skin corrosion study (OECD TG 431) with a mean tissue viability of <50 % in RhE after 3 minutes of exposure to 50 µL of the chemical (REACHb);
- ricinoleamidopropyl dimethylamine was positive in a skin irritation study (OECD TG 439) with a mean tissue viability of <50 % in RhE after 42 minute exposure (followed by 42 minute recovery) to 16 µL of the chemical (REACHd);

- ricinoleamidopropyl dimethylamine was negative in a skin corrosion study (OECD TG 431) with a mean tissue viability of >50 % and >15 % in RhE after 3 minutes and 1 hour of exposure, respectively (volume not reported) (REACHd);
- oleamidopropyl dimethylamine was negative in a skin corrosion study (OECD TG 431) with a mean tissue viability of >50 % and ≤100 % in RhE after 3 minutes and 1 hour of exposure to 50 µL of the chemical, respectively (REACHa);
- behenamidopropyl dimethylamine was negative in a skin corrosion: transcutaneous electrical resistance study (TER) (OECD TG 430) with a mean electrical resistance of 16.33 ± 2.5 kO in rat skin tissue after 24 hours exposure to the chemical in 150 µL of water (REACHe); and
- stearamidopropyl dimethylamine was negative in a skin irritation study (OECD TG 439) with a relative mean tissue viability of 108 % in RhE after 15 minutes of exposure (followed by 42 hours recovery) to 10.6–14.5 mg of the chemical (CIR, 2019; REACHc).

Variability is also seen in the in vitro tests, and measured responses are overall less severe than what was seen in some in vivo tests. Therefore, the results and conclusions from the in vivo studies are preferred.

Eye

Based on in vitro and in vivo studies, stearamidopropyl dimethylamine, ricinoleamidopropyl dimethylamine, behenamidopropyl dimethylamine and cocamidopropyl dimethylamine are expected to cause irreversible eye damage. The different fatty acid substituents of these chemicals cover the structural variation across all the chemicals in this group. Variability between solids and liquids will be less relevant in the aqueous environment of the eyes. Therefore, it is expected that all 14 members will cause irreversible eye damage consistent with corrosivity.

Stearamidopropyl dimethylamine

In an in vitro eye irritation study conducted according to OECD TG 437 (bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants; BCOP assay), ~311 mg of the chemical in solid form was applied to 3 bovine corneae for 240 ± 10 minutes. A mean in vitro irritation score (IVIS) of 29 was reported. A mean IVIS of ≥55.1 is considered to be corrosive or a severe irritant to eye. Based on the criteria of the assay, the chemical was not considered to be corrosive or a severe irritant to the eye (REACHc).

No or minimal irritation was observed in 2 in vitro EpiOcular irritation studies using the chemical in a pre-shave scrub (0.45 %) or in a hair conditioner (2 %), diluted to 10 % solution (CIR, 2019). No other experimental details are available for these studies.

In an in vivo eye irritation study conducted according to OECD TG 405, 56.3 mg (~0.1 mL) of the chemical was instilled into the conjunctival sac of one eye of a young adult male New Zealand White rabbit while the other eye served as the control. The observation period was terminated after 24 hours due to ethical reasons. The eye lesions consisted of an injury of the cornea, iridial irritation and severe effects on the conjunctivae (grey/white coloration indicating necrosis, redness, chemosis and bloody discharge). Scoring of the cornea, iris and eyelids was not possible due to swelling and exudation. Due to the severity of effects in this animal, no further animals were tested. The chemical was considered to cause irreversible eye damage (CIR, 2019; REACHc).

Ricinoleamidopropyl dimethylamine

In an in vitro eye irritation study conducted according to OECD TG 492 (reconstructed human cornea-like epithelium (RhCE) test for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage), 50 µL of undiluted chemical was applied to 2 tissue replicates for 30 minutes. The mean percent tissue viability after exposure and post-exposure incubation (120 minutes) was <60 %. Based on the criteria of the assay, the chemical was considered as requiring classification for eye irritation or serious eye damage according to the UN GHS classification system (REACHd). Further testings are required to determine accurate classification of the chemical.

Behenamidopropyl dimethylamine

No or minimal irritation was observed in 2 in vitro EpiOcular irritation studies using the chemical in shampoos (0.3 %) diluted to 10 % solution (CIR, 2019). No other experimental details are available for these studies.

An in vivo eye irritation study was conducted in accordance with OECD TG 405 using a chemical mixture of 50:50 (w/w %) stearamidopropyl dimethylamine and behenamidopropyl dimethylamine. The mixture (100 mg) was instilled into the conjunctival

sac of the left eye of a young adult female New Zealand White rabbit for 48 hours, while the other eye served as the control. The eye was washed with saline at 24 and 48 hours. The mean scores for corneal opacity, iris, redness and chemiosis of the conjunctivae were not calculated due to the severity of the effects on the animal after 48 hours. No further animals were tested. Based on these observations, the chemical was considered to cause irreversible damage to eye (REACHe).

Cocamidopropyl dimethylamine

In a non-guideline eye irritation study, 4 male white rabbits were treated with a single application of 0.1 mL of the chemical diluted to 1 % in distilled water in one eye. The eye was not rinsed after application. Moderate conjunctivae reaction was recorded at 1 and 6 hours after application, but was fully reversible after 48 hours. The chemical was considered to be an irritant to eyes (Galleria Chemica). However, the corrosivity of the chemical cannot be excluded due to higher concentrations not tested. Based on its property as a skin corrosive, it is expected that the chemical would cause irreversible eye damage at high concentrations.

Observation in humans

Oleamidopropyl dimethylamine

No dermal irritation or other adverse effects were observed in 102 subjects treated with 0.1 % of the chemical in an aqueous solution for 48 hours semi-occluded patch test (CIR, 2019). No other details are available for the study.

Stearamidopropyl dimethylamine

No dermal irritation was observed in 30 male subjects treated with the chemical in a pre-shave scrub (0.045 %) daily for 2 weeks (CIR, 2019). No other details are available for the study.

Behenamidopropyl dimethylamine

No dermal irritation or other adverse effects were observed in 2 studies where female subjects (n=28) were treated with the chemical 0.3 % in a shampoo or 3 % in a hair conditioner daily for 2 weeks (CIR, 2019). No other details are available for these studies.

Sensitisation

Skin Sensitisation

The skin sensitisation potential of the chemicals in this group is expected to be driven by the amine group and the surfactant property of the chemicals. Although an in vitro and some in vivo studies gave negative results, based on the weight of evidence on the available animal and human case studies (see **Observation in Humans** section), it is expected that all 14 chemicals in this group are potential skin sensitisers. Therefore, these chemicals warrant classification (see **Recommendation** section).

Oleamidopropyl dimethylamine

In an in vivo skin sensitisation study conducted according to OECD TG 406 (guinea pig maximisation test (GPMT)), female Dunkin-Hartley guinea pigs (n=11) were treated with the chemical via intradermic (ID) injection (0.3906 %, day 0) and topical administration (0.5 mL of 100 %, day 7) at induction phase. The animals were then topically challenged with the chemical at 0.7813 or 1.5625 % concentrations for 24 hours (day 20). Slight to moderate oedema and a significant macroscopical cutaneous reaction were observed in the skin area treated with both concentrations of the chemical in all animals (REACHa).

Stearamidopropyl dimethylamine

In an in vivo skin sensitisation study conducted according to OECD TG 406 (GPMT), female Dunkin-Hartley guinea pigs (n=10) were treated with the chemical via ID injection (2.5 %, day 0) and topical administration (1 %, day 7) at induction phase. The animals were topically challenged with the chemical at 2 % concentration for 24 hours (day 20). No skin reactions were observed in the challenged animals (CIR, 2019; REACHc).

In an in vivo skin sensitisation study conducted according to OECD TG 406 (Buehler test), Dunkin-Hartley guinea pigs (n=20) were treated with 1 % (w/v) of the chemical in 80 % ethanol under occlusion for 6 hours once a week for a total of 3 exposures. The animals were challenged with 0.25 % (w/v) of the chemical in acetone after 2 weeks, followed by a rechallenge with 0.25, 0.125 and 0.0625 % (w/v) after 13 days. One animal had a positive response to the chemical at 0.25 % (CIR, 2012).

Ricinoleamidopropyl dimethylamine

In a non-guideline in vitro SENS-IS assay (Cottrez et al., 2015), RhE tissues were treated with the chemical at concentrations of 0.1, 1, 10 or 50 % (v/v) in dimethylsulfoxide (DMSO). Gene expression was not interpretable due to tissue damage at 50 % concentration. Based on the number of over-expressed genes (>7) in RhE tissues, the chemical was not considered a skin sensitiser under the test conditions (REACHd).

Cocamidopropyl dimethylamine

The sensitisation potential of lauramidopropyl dimethylamine was determined using the read-across data from cocamidopropyl dimethylamine (C6–C18) containing impurities 0.05 % (w/w) glycerol and 6 mg/kg DMAPA. In an in vivo skin sensitisation study conducted according to OECD TG 406 (GPMT), female Dunkin-Hartley guinea pigs (n=10) were treated with the chemical via ID injection (0.05 %, day 0) and topical administration (5 %, day 7) at induction phase. The animals were then topically challenged with the chemical at 1 % concentration for 24 hours (day 20). Slight to moderate erythema and oedema were observed in 6 out of 10 animals after 48 hours observation (REACHb).

In 2 in vivo skin sensitisation studies (OECD TG 406; GPMT), Dunkin-Hartley guinea pigs (6 females, 4 males) were treated with the chemical via ID injection (0.1 or 0.025 %, day 0) and topical administration (5 or 1 %, day 7) at induction phase. The animals were topically challenged with the chemical at the concentration 0.5 % in acetone/PEG400 for 24 hours (day 21). Up to 2 more challenges were made at 1-week interval after the first challenge. In the first study, moderate erythema and oedema were observed in 80 % of the tested animals after the third challenge. In the second study, slight to moderate erythema and oedema were observed in 30 % of the tested animals after the second challenge (CIR, 2019).

Tallamidopropyl dimethylamine

In an in vivo skin sensitisation study conducted according to OECD TG 406 (GPMT), Dunkin-Hartley guinea pigs (n=10/sex) were treated with the chemical via ID injection (0.1 %, day 0) and topical administration (10 % w/w in ethanol, day 7) at induction phase. The animals were topically challenged with the chemical at the concentration 1 % (w/w) in acetone for 24 hours (day 22). No skin reactions were observed in the challenged animals (REACHf).

Observation in humans

Stearamidopropyl dimethylamine

In 12 human repeat insult patch tests (HRIPT), human subjects (n=50–122) were treated semi-occlusively or occlusively with the chemical present in various body lotions and hair conditioners (0.045–2 %). Mild erythema was observed in several subjects in 2 studies and the chemical was considered to be a skin irritant in these studies. No dermal sensitisation effects were observed in all studies (CIR, 2019).

Behenamidopropyl dimethylamine

In 2 HRIPT studies, human subjects (n=103 or 106) were treated occlusively with the chemical present in a shampoo (0.3 %). No dermal sensitisation or other adverse events were observed in these studies (CIR, 2019).

Case studies

In the Netherlands, 13 patients allergic to the cationic emulsifier oleamidopropyl dimethylamine were tested with a series of related surfactants to investigate its cross-reaction pattern. All 13 patients reacted to oleamidopropyl dimethylamine (100 %). One patient had no reactions to any of the other substances, but 12 patients had reactions to lauramidopropyl dimethylamine (75 %), and myristamidopropyl dimethylamine (46 %), isostearamidopropyl dimethylamine (38 %), minkamidopropyl dimethylamine (38 %), cocamidopropyl dimethylamine (38 %), palmitamidopropyl dimethylamine (15 %) and behenamidopropyl

dimethylamine (15 %). A certain pattern of cross-reactivity was recognised. The author suggested some of these reactions may be attributable to irritant reactions (CIR, 2019; REACHf).

In 3 case reports, 5 patients were treated for allergic contact dermatitis around the eyes and/or the body after using certain body lotions. Patch testing showed that patients had positive reactions to oleamidopropyl dimethylamine (CIR, 2019).

In a 10-year retrospective study, the North American Contact Dermatitis Group investigated the possible allergens for patients with allergic eyelid dermatitis. Patch testing showed that 10. 9 and 4.3 % of patients tested had relevant reactions to oleamidopropyl dimethylamine and cocamidopropyl dimethylamine, respectively (CIR, 2019).

In a review of 5-year (2002–2009) patch test records of 1092 patients at the Finnish Institute of Occupational Health, 1.2 and 0.7 % of the patients showed allergic reactions to cocamidopropyl dimethylamine and oleamidopropyl dimethylamine, respectively (Suuronen et al., 2012).

Repeated Dose Toxicity

Oral

Based on the available data, the chemicals in this group are not considered to cause serious damage to human health from repeated oral exposure. The toxicity effects observed in the animals are related to local irritation due to the corrosive nature of these chemicals.

Oleamidopropyl dimethylamine

In a 28-day repeated dose oral toxicity study conducted according to OECD TG 407, Wistar rats (n=5/sex/dose) received the chemical via gavage at concentrations of 0, 10, 50 or 150 mg/kg bw/day. No mortality occurred during the study. No significant treatment-related changes in histopathological findings were observed. Salivation and respiration sounds were observed in the high dose group. Under the test conditions, the reported no observed adverse effect level (NOAEL) was 50 mg/kg bw/day in rats (REACHa).

Stearamidopropyl dimethylamine

In a 14-day dose range finding study conducted as part of a subacute repeated dose oral toxicity study (OECD TG 407), Crl:WI(Han) rats (n=3/sex/dose) received the chemical in propylene glycol via gavage at concentrations of 0, 50, 200 or 500 mg/kg bw/day for 14 days. No mortality occurred in the low and mid dose groups. No treatment-related clinical signs of toxicity were observed and histopathology of organs showed no significant changes in the low and mid dose groups. All animals in high dose group were terminated for humane reasons between day 6 and 8. Necropsy of these animals showed gelatinous contents in the gastrointestinal tract, stomach ulceration and/or hyperplasia of the squamous epithelium of the fore stomach. Other histopathological effects included lymphoid atrophy of the thymus, foamy macrophages and sinusoidal dilation and congestion, and erythrophagocytosis in the mesenteric lymph node (CIR, 2019; REACHc). The effects observed in the high dose group are likely to be driven by the corrosive nature of the chemical. For more information, see **the Reproductive and developmental toxicity** section for this chemical.

Cocamidopropyl dimethylamine

In a 29-day repeated dose oral toxicity study conducted according to OECD TG 407, Sprague-Dawley rats (n=5–10/sex/dose) received cocamidopropyl dimethylamine in corn oil via gavage at concentrations of 0, 30, 60 or 120 mg/kg bw/day. For the control and high dose groups, half of the animals were kept for a further 4-week treatment-free period for observation of reversibility, persistence or delayed occurrence of local and systemic effects. No mortality occurred during the study. Observed clinical signs included ptyalism, loud breathing and piloerection in some of the animals in treated groups. Microscopic examination revealed signs of pronounced irritation in the forestomach of animals treated with 60 or 120 mg/kg/day. These consisted of acanthosis, hyperkeratosis, erosion/ulcer, oedema with mixed infiltrate of inflammatory cells in the submucosa. Changes in the forestomach were present with low severity and incidence in the low dose group. Under test conditions, the reported NOAEL with respect to systemic toxic effects was 60 mg/kg bw/day in rats. The NOAEL with respect to local toxicity was not established due to irritation observed in the forestomach of all treated groups (REACHe).

Tallamidopropyl dimethylamine

In a 28-day repeated dose oral toxicity study conducted according to OECD TG 407, Wistar rats (n=5/sex/dose) received the chemical via gavage at concentrations of 0, 10, 50 or 150 mg/kg bw/day. No mortality occurred during the study. No significant treatment-related changes in clinical and histopathological findings were observed. Under the test conditions, the reported NOAEL was 150 mg/kg bw/day in rats (REACHf).

Dermal

Based on the limited available data, the chemicals in this group are not considered to cause serious damage to human health from repeated dermal exposure. The effects observed are related to local irritation due to the corrosive nature of the chemical.

Stearamidopropyl dimethylamine

In a subchronic 90-day repeat dose dermal toxicity study conducted similarly to OECD TG 411, the chemical in 30% ethanol at doses equivalent to 0, 5 and 200 mg/kg bw/day was applied to the intact skin (non-occlusive) of New Zealand White rabbits (n=5/sex/dose). The animals were treated once daily, 5 days/week for 13 consecutive weeks. The treated skin was washed with water and gently blotted dry after 4 hours of exposure. The animals were collared to prevent oral ingestion of the chemical. No mortality occurred during the study. No significant treatment-related changes in body weight and body-weight gain, or absolute and relative weight of liver, kidney and adrenals were observed. Slight to moderate erythema, slight oedema, slight desquamation and slight fissuring were observed on the skin of the treated groups. Histopathological findings included minimal acanthosis and hyperkeratosis at the treatment sites (CIR, 2019; REACHc). The effects observed are likely to be driven by the corrosive nature of the chemical. For more information, see **the Reproductive and developmental toxicity** section for this chemical.

Inhalation

No data are available.

Genotoxicity

Based on the negative results from the available in vitro studies, the chemicals in this group are not considered to be genotoxic. No in vivo data are available.

Negative results were observed in the following in vitro genotoxicity studies tested up to cytotoxic concentrations:

Oleamidopropyl dimethylamine (REACHa)

- a bacterial reverse mutation assay (OECD TG 471) in *Salmonella typhimurium* strains TA97a, 98, 100, 102 and 1537, with and without metabolic activation (S9) at concentrations of 12.5–50 µg/plate;
- a mammalian gene mutation assay (OECD TG 476) at the hypoxanthine-guanine phosphoribosyl transferase (HPRT) locus of Chinese hamster ovary (CHO) cells with and without metabolic activation at concentrations of 0–20 µg/mL; and
- a mammalian chromosome aberration (CA) assay (OECD TG 437) in Chinese hamster lung fibroblasts (V79) cells with and without metabolic activation at concentrations of 0–20 µg/mL.

Stearamidopropyl dimethylamine (CIR, 2019; REACHc)

- a bacterial reverse mutation assay (OECD TG 471) in *S. typhimurium* strains TA98, 100, 1535 and 1537 at concentrations of 0–250 µg/plate, and in *Escherichia coli* WP2uvrA at concentrations of 0–500 µg/plate with and without metabolic activation;
- a mammalian gene mutation assay (OECD TG 467) at the thymidine kinase (TK) locus in L5178Y mouse lymphoma with and without metabolic activation at concentrations of 0–60 µg/mL; and

- a mammalian CA assay (OECD TG 473) in human lymphocytes with and without metabolic activation at concentrations of 0–25 µg/mL.

Ricinoleamidopropyl dimethylamine (REACHd)

- a bacterial reverse mutation assay (OECD TG 471) in *S. typhimurium* strains TA98, 100, 1535 and 1537, and *E. coli* WP2uvrA, with and without metabolic activation at concentrations of 0–50 µg/plate.

Behenamidopropyl dimethylamine (REACHe)

- a bacterial reverse mutation assay equivalent to OECD TG 471 in *S. typhimurium* strains TA98, 100, 1535 and 1537 at concentrations of 39–1250 µg/plate, and in *E. coli* WP2uvrA at concentrations of 156–5000 µg/plate with and without metabolic activation.

Cocamidopropyl dimethylamine (Galleria Chemica)

- a bacterial reverse mutation assay similar to OECD TG 471 in *S. typhimurium* strains TA98, 100, 1535 and 1537, with and without metabolic activation at concentrations of 0.8–5000 µg/plate.

Tallamidopropyl dimethylamine (REACHf)

- a bacterial reverse mutation assay (OECD TG 471) in *S. typhimurium* strains TA98, 100, 1535 and 1537 at concentrations of 0–50 µg/plate without metabolic activation and 0–150 µg/plate with metabolic activation;
- a mammalian gene mutation assay similar to OECD TG 476 at the HPRT locus of CHO cells with and without metabolic activation at concentrations of 0–20 µg/mL; and
- a mammalian CA assay (OECD TG 473) in Chinese hamster lung fibroblasts (V79) cells with and without metabolic activation at concentrations of 0–150 µg/mL.

Carcinogenicity

No studies are available on the carcinogenicity of fatty acid amidopropyl dimethylamines.

Reproductive and Developmental Toxicity

Based on the available data, the chemicals in this group are not expected to cause developmental and reproductive toxicity from repeated oral and/or dermal exposure routes. The effects observed are related to secondary maternal toxicity derived from local irritation due to the corrosive nature of the chemicals.

Oral

Oleamidopropyl dimethylamine

In a reproductive/developmental toxicity screening study conducted in accordance with OECD TG 421, Wistar rats (n=10/sex/group) were administered the chemical via gavage at doses 0, 25, 75 or 200 mg/kg bw/day. Males were treated for 28 days, while females were treated from the beginning of the study until day 4 of lactation. Statistically significant body weight loss and reduced body weight gain were observed in males in the high dose group. Fertility indices decreased to 80 % in both males and females in the high dose group. However, gross and histopathological examinations of the animals did not show relevant treatment-related changes for impaired fertility. A significant increase in pup mortality during lactation was observed in the high dose group. Gross necropsy revealed no treatment-related effects. Based on the results, a reported NOAEL of 75 mg/kg bw/day was determined for both reproductive and developmental toxicity (REACHa).

Stearamidopropyl dimethylamine

In a 14-day dose range study conducted as part of a subacute repeated dose oral toxicity study (OECD TG 407) (see **Repeated Dose Toxicity: Oral** section), the following effects on male reproductive organs were noted in rats treated with 500 mg/kg bw/day of the chemical: absence of spermiation and degeneration of spermatids in the testes; oligospermia and seminiferous cell debris in the epididymides; and reduced contents in the prostate and seminal vesicles corresponding to a reduced size of seminal vesicles; and prostate and epididymides at necropsy (CIR, 2109; REACHc). These observations are not likely to be a direct effect on the reproductive toxicity, but rather secondary toxicity effects caused by the corrosive nature of the chemical.

The dose range identified from the above study was used to conduct a combined repeated dose and reproduction/developmental toxicity screening test (OECD TG 421). Wistar rats (n=10/sex/group) were administered the chemical via gavage at concentrations 0, 20, 70 or 200 mg/kg bw/day. Males were treated for 28 days while females were treated from the beginning of the study until day 4 of lactation. Statistically significant body weight loss and reduced body weight gain were observed in both males and females in the high dose group. A statistically significant lower number of implantation sites, and subsequent lower number of living pups were observed for females at 200 mg/kg bw/day. No other treatment-related changes were noted in any of the remaining reproductive parameters investigated in this study (i.e. mating, fertility and conception indices and precoital time, testes and epididymides weights, spermatogenic staging profiles). Based on these results, a parental NOAEL of 70 mg/kg bw/day, fertility NOAELs of 70 mg/kg day/bw (females) and 200 mg/kg day/bw (males), and a developmental NOAEL of 200 mg/kg day/bw were determined (CIR, 2019; REACHc).

Dermal

Stearamidopropyl dimethylamine

In a subchronic 90-day repeated dose dermal toxicity study in rabbits conducted similarly to OECD TG 411(see **Repeated Dose Toxicity: Dermal** section), no treatment-related findings concerning the reproductive organs were observed. Under the test conditions, the reported dermal NOAEL was 200 mg/kg bw/day in rabbits (CIR, 2019; REACHc).

In a prenatal developmental toxicity study conducted similarly to OECD TG 414, female New Zealand White rabbits (n=20/dose) received daily topical application of the chemical in 30 % isopropanol at doses 0, 5, 100 or 200 mg/kg bw/day (0.2 mL/kg dose volume) from days 7–18 of gestation. The test sites were not occluded and were rinsed with water 2 hour after the exposure. The animals were collared to prevent oral ingestion of the chemical. No mortality occurred during the study. The test material did not adversely affect pregnancy incidence or average numbers of corpora lutea or resorptions. No treatment-related foetal variations at gross external, soft tissue or skeletal examination were observed. Based on the experimental data, the maternal NOAEL was determined to be 100 mg/kg bw/day and the developmental NOAEL was 200 mg/kg bw/day in rabbits (CIR, 2019; REACHc).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic acute effects (acute toxicity from oral exposure) and local effects (corrosivity and skin sensitisation). These chemicals can also cause harmful systemic effects following a single oral exposure.

Public Risk Characterisation

Although use in Australia is not known (except oleamidopropyl dimethylamine), these chemicals are reported to be used in cosmetic/domestic products overseas.

The public could be exposed to these chemicals through potential cosmetic use. However, based on the information available from the National Library of Medicine (NLM) Household Products Database and the Cosmetic Ingredient Review (CIR), concentrations present in these products are not considered to be sufficiently high to cause corrosive or sensitisation effects. Therefore, these chemicals are not considered to pose an unreasonable risk to public health given that normal precautions are taken to avoid direct eye contact.

Occupational Risk Characterisation

During product formulation, dermal and ocular 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 these chemicals at lower concentrations could also occur while using formulated products containing these chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical local health effects, these chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure are implemented. These 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 Chemical Information System (HCIS) (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

Work Health and Safety

These chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below.

The hazard classifications for Corrosion/Irritation – Category 1 (H314; Causes severe skin burns and eye damage) and Sensitisation – Category 1B (H317; May cause an allergic skin reaction) apply to all the chemicals in this group.

In addition, the hazard classification for Acute Toxicity (Oral) – Category 4 (H302; Harmful if swallowed) applies to lauramidopropyl dimethylamine (CAS No. 3179-80-4), stearamidopropyl dimethylamine (CAS No. 7651-02-7) and cocamidopropyl dimethylamine (CAS No. 68140-01-2).

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Not Applicable	Causes severe skin burns and eye damage - Cat. 1 (H314)
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1B (H317)

[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 these chemicals should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from dermal and ocular exposure to these 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:

- 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.

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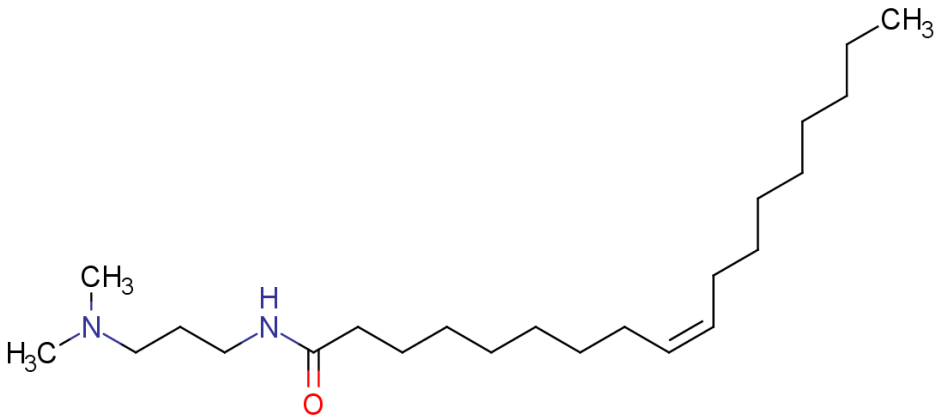
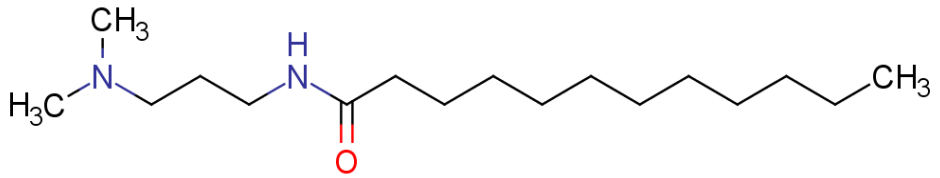
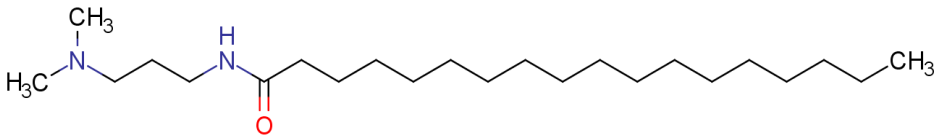
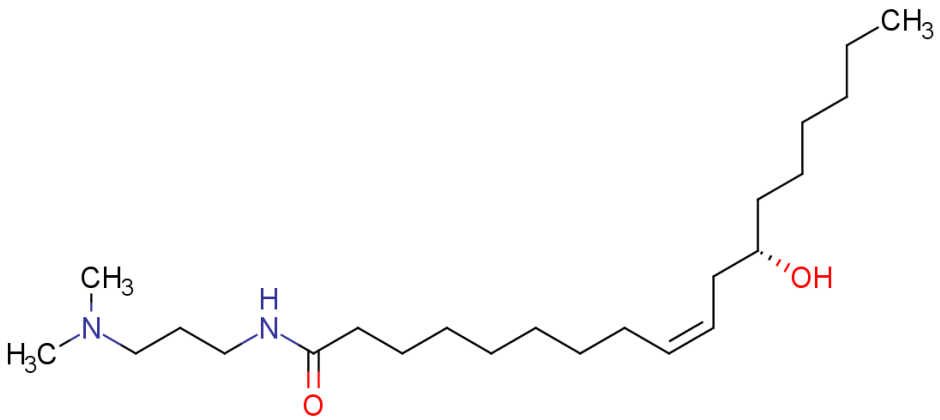
Last Update 12 December 2019

Chemical Identities

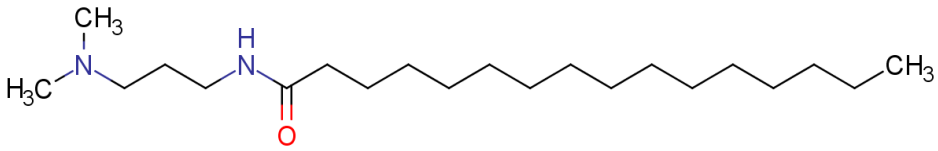
Chemical Name in the Inventory and Synonyms	**9-Octadecenamide, N-[3-(dimethylamino)propyl]-, (Z)-** oleamidopropyl dimethylamine (Z)-N-[3-(dimethylamino)propyl]octadec-9-enamide N-(3-(dimethylamino)propyl)oleamide lexamine O-13
CAS Number	109-28-4
Structural Formula	
Molecular Formula	C23H46N2O
Molecular Weight	366.62

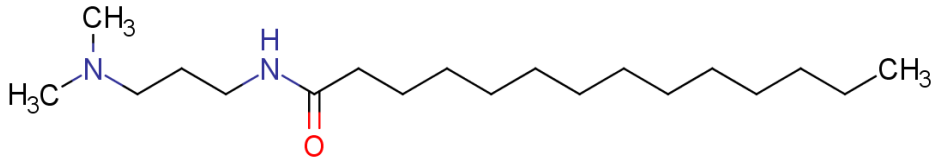
Chemical Name in the Inventory and Synonyms	**Dodecanamide, N-[3-(dimethylamino)propyl]-** lauramidopropyl dimethylamine N-[3-(dimethylamino)propyl]dodecanamide N-[3-(dimethylamino)propyl]lauramide lexamine L-13
CAS Number	3179-80-4
Structural Formula	
Molecular Formula	C17H36N2O
Molecular Weight	284.48

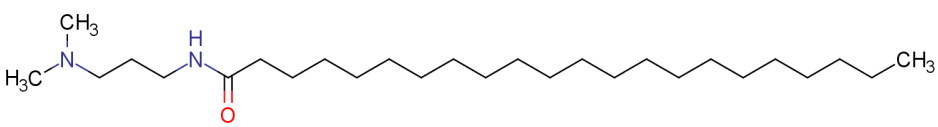
Chemical Name in the Inventory and Synonyms	**Octadecanamide, N-[3-(dimethylamino)propyl]-** stearamidopropyl dimethylamine N-[3-(dimethylamino)propyl]octadecanamide N-[3-(dimethylamino)propyl]stearamide lexamine S-13
CAS Number	7651-02-7
Structural Formula	
Molecular Formula	C23H48N2O
Molecular Weight	368.64

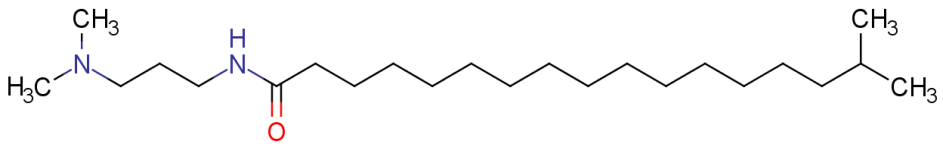
Chemical Name in the Inventory and Synonyms	**9-Octadecenamide, N-[3-(dimethylamino)propyl]-12-hydroxy-, [R-(Z)]-** ricinoleamidopropyl dimethylamine (Z,12R)-N-[3-(dimethylamino)propyl]-12-hydroxyoctadec-9-enamide N-(3-(dimethylamino)propyl)ricinoleamide
CAS Number	20457-75-4
Structural Formula	
Molecular Formula	C23H46N2O2
Molecular Weight	382.65

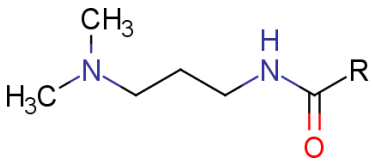
Chemical Name in the Inventory and Synonyms	**Hexadecanamide, N-[3-(dimethylamino)propyl]-** palmitamidopropyl dimethylamine N-[3-(dimethylamino)propyl]hexadecanamide dimethylaminopropyl palmitamide

CAS Number	39669-97-1
Structural Formula	
Molecular Formula	C21H44N2O
Molecular Weight	340.59

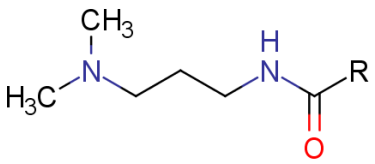
Chemical Name in the Inventory and Synonyms	**Tetradecanamide, N-[3-(dimethylamino)propyl]-** myristamidopropyl dimethylamine N-[3-(dimethylamino)propyl]tetradecanamide N-[3-(dimethylamino)propyl]myristamide aldox
CAS Number	45267-19-4
Structural Formula	
Molecular Formula	C19H40N2O
Molecular Weight	312.53

Chemical Name in the Inventory and Synonyms	**Docosanamide, N-[3-(dimethylamino)propyl]-** behenamidopropyl dimethylamine N-[3-(dimethylamino)propyl]docosanamide dimethylaminopropyl behenamide
CAS Number	60270-33-9
Structural Formula	
Molecular Formula	C27H56N2O
Molecular Weight	424.75

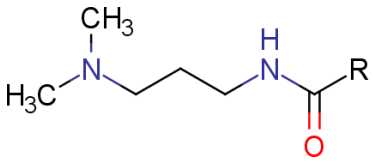
Chemical Name in the Inventory and Synonyms	**Isooctadecanamide, N-[3-(dimethylamino)propyl]-** isostearamidopropyl dimethylamine N-[3-(dimethylamino)propyl]-16-methylheptadecanamide
CAS Number	67799-04-6
Structural Formula	
Molecular Formula	C23H48N2O
Molecular Weight	368.65

Chemical Name in the Inventory and Synonyms	**Amides, coco, N-[3-(dimethylamino)propyl]** cocamidopropyl dimethylamine N-(3-(dimethylamino)propyl)coco amides
CAS Number	68140-01-2
Structural Formula	 R = various fattty acid chain lengths derived from coconut oil
Molecular Formula	Unspecified

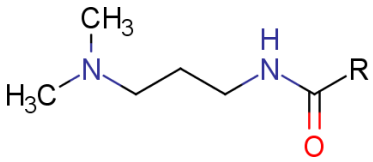
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Amides, soya, N-[3-(dimethylamino)propyl]** soyamidopropyl dimethylamine dimethylaminopropyl soyamide
CAS Number	68188-30-7
Structural Formula	 R = various fattty acid chain lengths derived from soy
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Amides, tall oil fatty, N-[3-(dimethylamino)propyl]** tallamidopropyl dimethylamine dimethylaminopropyltallamide
CAS Number	68650-79-3
Structural Formula	

	 R = various fattty acid chain lengths derived from tall oil
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Amides, mink oil, N-[3-(dimethylamino)propyl]** minkamidopropyl dimethylamine dimethylaminopropyl mink fatty acids amide
CAS Number	68953-11-7
Structural Formula	

	 R = various fattty acid chain lengths derived from mink oil
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Amides, tallow, hydrogenated, N-[(dimethylamino)propyl]** hydrogenated tallow acids, dimethylaminopropylamide
CAS Number	69013-24-7
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Amides, C8-22, N-[3-(dimethylamino)propyl]**
CAS Number	84082-43-9
Structural Formula	**No Structural Diagram Available**
Molecular Formula	Unspecified
Molecular Weight	

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