Sodium and ammonium laureth sulfate: Human health tier II assessment

28 June 2013

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt	3088-31-1
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-(dodecyloxy)-, sodium salt (1:1)	9004-82-4
Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]-, hydrogen sulfate, sodium salt	13150-00-0
Ethanol, 2-(dodecyloxy)-, hydrogen sulfate, sodium salt	15826-16-1
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-(dodecyloxy)-, ammonium salt	32612-48-9
3,6,9,12,15,18,21,24,27,30,33,36-Dodecaoxaoctatetracontan-1-ol, hydrogen sulfate, sodium salt	66161-57-7

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

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

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

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are structurally related salts of sulfated ethoxylated lauryl alcohol. The synthesis of the chemicals occurs through similar processes. Lauryl alcohol is ethoxylated with ethylene oxide to form a polyethoxy ether. The terminal alcohol group is then sulfated with sulfur trioxide. The product is neutralised with either sodium or ammonium hydroxide, producing the chemicals of this group. The sodium and ammonium ions are not expected to significantly affect the hazardous properties of the chemicals.

The number of ethoxylate units usually has an average value between one and four. Sodium laureth sulfate, CAS No. 9004-82-4, is a generic CAS registration number that includes the group of chemicals with CAS Nos 15826-16-1, 3088-31-1, 13150-00-0, and 66161-57-7, where they have an average of one, two, three, and 12 ethoxylate units, respectively.

Although some of the chemicals of this group are polymers according to the definition in the *Industrial Chemicals (Notification and Assessment) Act (1989)*, the individually named members do not necessarily meet the polymer of low concern (PLC)

number-average molecular weight criteria (< 1000 Da). Lower molecular weight forms of the generic chemicals (CAS Nos 9004-82-4 and 32612-48-9) are expected to be used in products.

Import, Manufacture and Use

Australian

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

The chemicals have reported use as a cosmetic ingredient.

The chemicals have reported use as cleaning/washing agents and additives.

The chemicals have reported use as surface-active agents.

Sodium laureth sulfate (CAS No. 9004-82-4) is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 1000 and 9999 tonnes.

International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers, the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR), Galleria Chemica, Substances in preparations in Nordic countries (SPIN) database, the European Commission Cosmetic Substances and Ingredients (CosIng) database, United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) directory, and other data sources via eChemPortal, including the US Environmental Protection Agency's (EPA) Aggregated Computer Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemicals have reported use in cosmetics functioning as emulsifiers, stabilisers and solubilisers.

The chemicals have reported domestic use including:

- cleaning/washing agents;
- bleaching agents;
- emulsifying agent; and
- surfactants.

Most of the chemicals of this group have reported commercial use including:

- adhesives and binding agents;
- construction and surface treatment materials;
- concentrate surfactant;
- flame retardants and extinguishing agents;
- lubricants and additives; and
- paints, lacquers and varnishes.

Sodium laureth sulfate (CAS No. 9004-82-4) has reported site-limited use as an electroplating agent.

The following non-industrial uses have been identified internationally:

- pharmaceuticals;
- agricultural pesticides;
- preservatives; and
- food/feedstuff flavourings and nutrients.

Restrictions

Australian

No known restrictions have been identified. However, the chemicals are synthesised through processes which may result in 1,4-dioxane as an impurity. This impurity is controlled through listing in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) in Schedule 6, with scheduling labelling requirements applying above 100 ppm (Appendix G).

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

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

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Acute Toxicity

Oral

The chemicals in this group were reported to be of moderate acute toxicity in animal tests, with reported oral LD50s in rats. LD50s ranged from 630 – >2000 mg/kg bw (ChemIDplus Advanced; CIR, 1983; Tusing, 1962; Walker AIT et al., 1967; HPV, 2006). Observed sub-lethal effects included diarrhoea and central nervous system depression.

Dermal

There are no reliable data available. In a study reported in CIR (1983), ammonium laureth sulfate (as a component of a formulated product) was tested at 10 mg/kg bw on rabbits. There were no deaths during the observation period, or gross pathological findings at necropsy.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

In studies reported in CIR (1983), most of the chemicals in this group were tested on intact rabbit skin in concentrations between 5–61 %, with adverse reactions ranging from slight to severe irritation. Irritation severity increased with increasing concentration.

In these studies, sodium laureth sulfate was applied in an occluded patch test in rabbits and evaluated according to the Draize method after 24- and 48-hour contact periods. The chemical produced no irritation at 5–5.6 % concentration. Mild erythema and oedema were observed at 6–26 % concentration in some studies. However, in other studies severe irritation was induced at 15–30 % concentration.

In the studies of ammonium laureth sulfate, mild erythema was observed at 7.5–12 % concentration. Moderate to severe irritation was observed at 12–61 % concentration.

In a study reported in HPV (2006) ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt (CAS No. 3088-31-1) was reported to be moderately irritating to the skin in a GLP compliant animal test similar to OECD TG 404. The test was applied to rabbits for a 24 hour application with a semi-occlusive dressing. Observed effects included atonia, blanching discolouration and spreading of irritative effects.

Eye Irritation

The chemicals in this group are eye irritants.

In studies reported in CIR (1983) that were similar to OECD TG 405, the eyes of rabbits were instilled with sodium laureth sulfate or ammonium laureth sulfate from 1.3–60 % concentration and evaluated according to the Draize method. Sodium laureth sulfate was mildly irritating to the eyes at concentrations between 1.3–7.5 % and moderately to severely irritating to the eyes at concentrations between 10–30 %. Studies in which the eyes were rinsed with water immediately after applying the test article showed significantly lower irritation than when the eyes were not washed. Ammonium laureth sulfate was mildly irritating to the eye at concentrations of 7.5–20 % and severely irritating to the eye at concentrations of 25–60 %.

In a study reported in HPV (2006), ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt (CAS No. 3088-31-1) was reported to be moderately irritating to the eye in a well-conducted animal test similar to OECD TG 405. Observed adverse effects included changes to the cornea, iris and conjunctiva.

Observation in humans

In studies reported in CIR (1983), sodium laureth sulfate caused low level irritation in subjects in a 24 hour occlusive patch test at 18 % concentration.

In a study reported in CIR (2010), ammonium laureth sulfate was not irritating in 20 subjects at 0.9–0.18 % concentration.

Sensitisation

Skin Sensitisation

The chemicals in this group are not expected to induce dermal sensitisation when applied topically.

In a study reported in CIR (1983), sodium laureth sulfate was not found to induce dermal sensitisation in guinea pigs when topically challenged in a test similar to OECD TG 406. Animals challenged by intradermal injection showed an adverse 'blistering effect' one hour after the challenge and a 'definite positive reaction' was observed in some animals 48 hours after the challenge.

Observation in humans

In a maximisation study reported in CIR (1983), 25 subjects were treated with a product containing 14.3 % sodium laureth sulfate under an occlusive patch on alternate days over a 10 day period. No evidence of sensitisation was reported after the product containing the chemical was applied during the challenge period.

Repeated Dose Toxicity

Oral

The chemicals in this group are expected to have low repeated dose toxicity when administered orally.

In a 13-week oral study in rats, a no observed adverse effect level (NOAEL) of 1000 ppm was reported for sodium laureth sulfate. In the study reported in CIR (1983), the rats (12 males and 12 females per group) were fed dietary levels of 40, 200, 1000, 5000 mg/kg bw/day of the chemical. Only the control and 5000 mg/kg bw/day groups were examined at necropsy. There was no evidence of histological or pathological changes at necropsy. Increased organ weights in males (kidney) and females (heart, liver and kidneys) were not statistically significant.

In a study reported in CIR (1983), sodium laureth sulfate was given to rats (30 animals per group) in a 105−week oral study at 0.1 and 0.5 % concentrations of the diet. After 52 weeks, 10 animals per group, and after 105 weeks the remaining surviving rats were sacrificed. There were no significant differences in gross or microscopic pathology in the experimental animals compared with the control groups.

Dermal

The chemicals of this group are expected to cause adverse local health effects by repeated dermal exposure. The NOAEL for local effects was 9 %.

In a study reported in CIR (1983), sodium laureth sulfate, at 0.9, 9, 30 or 60 % concentration, was applied daily to the skin of male Wistar rats. Seven out of 13 animals died between days 13–15 in the 60 % sodium laureth sulfate group. Histopathology of organs was not reported. After 33 days, surviving animals had parakeratosis, epidermal hyperplasia, acanthosis and disappearance of the granular layer. Animals in the 30 % sodium laureth sulfate group had mild erythema after 14 days. After 30 days, the epidermis showed epidermal hypertrophy, and an inflammatory reaction on the upper skin. No changes were seen at the lowest dose, and a mild skin reaction was seen at the 9 % dose on day 65.

Inhalation

No data are available.

Genotoxicity

Based on the weight of evidence from the available well conducted in vitro and in vivo genotoxicity studies on analogue chemicals reported in HERA (2003), the chemicals of this group are not considered genotoxic.

The structurally related chemical 2-propanol, 1,1'1''-nitrilotris-, compounds with poly-ethylene glycol hydrogen sulfate C12-14-alkyl ethers (CAS No. 174450-50-1), tested negative in an Ames test in *Salmonella typhimurium* (TA98, TA100, TA1535 and TA1537) following OECD TG 471 (bacterial reverse mutation assay).

The structurally related chemical, poly(oxy-1,2-ethanediyl), a-sulfo-?-hydroxy-, C12-15-alkyl ethers, sodium salts (CAS No. 125301-92-0), tested negative in an Ames test in *Salmonella typhimurium* (TA98, TA100, TA1535, TA1537) and *Escherichia coli* (WP2, WP2uvra) following OECD TG 471. This chemical did not induce gene mutations in mouse lymphoma cells following OECD TG 476 (in vitro mammalian cell gene mutation test). It was not clastogenic for Wistar rats in an alkaline elution assay measuring DNA single strand breaks, or for male mice in a dominant lethal assay measuring chromosomal anomalies.

Carcinogenicity

Based on a study reported in CIR (1983), sodium laureth sulfate was not likely to cause skin tumours.

In the study, 30 female Swiss mice were treated with 5 % of sodium laureth sulfate, applied twice weekly to the skin of the interscapular area for 105 weeks. There were no skin tumours or treatment-related mortalities.

The chemicals are synthesised through processes which may result in 1,4-dioxane as an impurity. This impurity is classified as a Carcinogen—Category 3 (R40—Limited evidence of a carcinogenic effect).

Reproductive and Developmental Toxicity

Based on a study reported in CIR (1983), chemicals of this group do not show reproductive or developmental toxicity.

In a two-generation reproduction toxicity study in rats with 0.1 % of sodium laureth sulfate, no adverse effect on fertility, litter size, lactation, or survival of off-spring was observed. There were no adverse findings at necropsy that were attributed to the test compound.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are the potential for skin and eye irritation. The irritant effects are similar to those produced by other surfactants, and the severity of irritation appears to increase directly with concentration of the surfactant.

Public Risk Characterisation

Chemicals in this group are not currently listed in the Poisons Standard (SUSMP) and there are no restrictions to use these in Australia.

The chemicals have reported use as domestic and cosmetic ingredients in Australia. International use suggests widespread and repeated exposure of the public to the chemicals through using rinse off cosmetic and domestic products, including products with spray applications. The chemicals are being used internationally at concentrations up to 50 % in rinse off cosmetic products, mostly in soaps and shampoos (CIR, 2010).

Where high concentrations are used in domestic and cosmetic products, accidental contact with the eye is a concern. Incidental oral exposure resulting in oral toxicity is considered unlikely given the types of products in which the chemicals are used, with the exception of liquid laundry detergent capsules.

Liquid laundry detergent capsules, which rapidly dissolves in contact with moisture, have caused accidental ingestion and eye exposure in children (Australian Competition and Consumer Commission (ACCC)). The exposure in these cases has the likelihood of being much greater than expected from bulk packaged laundry detergents. The ACCC has stated that the liquid laundry detergent capsules in their current form is highly attractive to children given the transparent packaging and bright colours. While there is some concern should these chemicals be used in liquid laundry detergent capsules in their current form, the ACCC, together with the relevant industry participants, are working to improve the safety and packaging of these products (Accord).

The concentration of the impurity 1,4-dioxane is controlled through listing in the Poisons Standard (SUSMP) in Schedule 6, with a limit of 100 ppm, above which the scheduling labelling requirements apply.

Occupational Risk Characterisation

During product formulation, dermal and ocular exposure of workers to chemicals in this group may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to these chemicals at lower concentrations may 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 systemic acute and local health effects of the chemicals in this group, the chemicals may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure to the chemical 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 HSIS (refer to **Recommendation section**).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended 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

The chemicals are surfactants and may increase the dermal absorption of other components of cosmetic products; care should be taken when formulating the chemicals into end-use products.

Work Health and Safety

The chemicals are recommended for classification and labelling under the current approved criteria and adopted Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This assessment does not consider classification of physical hazards and environmental hazards.

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

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

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to the instruction on the label. In particular, parents and carers are advised to keep liquid laundry detergent capsules away from children and to follow the Australian Competition and Consumer Commission's specific advice in this regard on their website—Product Safety Australia.

Advice for industry

Control measures

Control measures to minimise the risk from dermal and ocular exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storage, handling and use of a hazardous chemical are dependent on the physical form and the manner in which the chemicals are used. Examples of control measures which may minimise the risk include, but are not limited to:

- minimising manual processes and work tasks through automation of 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 selection of 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 hazardous chemical are prepared; and

- managing risks arising from storage, handling and use of 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 physical hazards of the chemicals have not been undertaken as part of this assessment.

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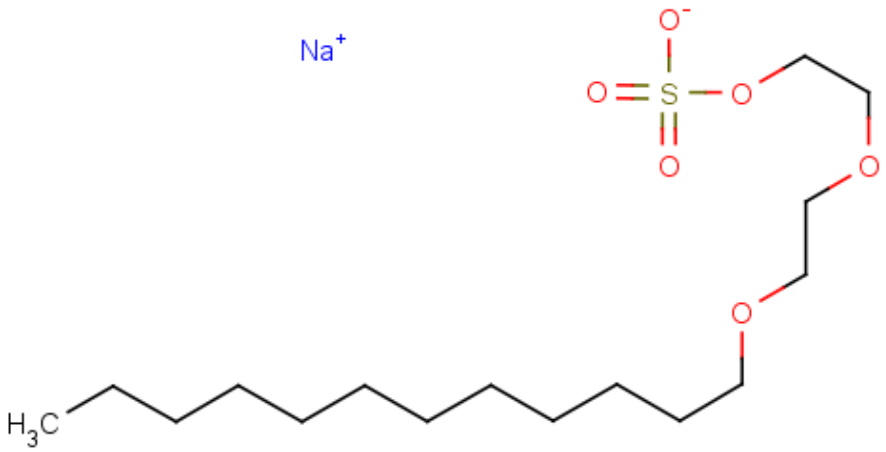
(Cited in CIR, 1983).

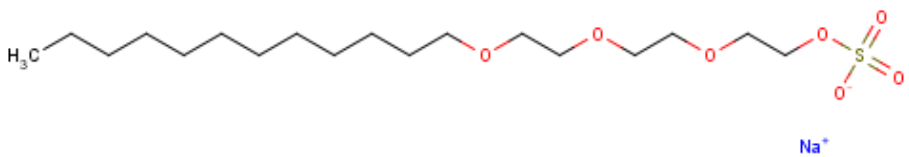
Last Update 28 June 2013

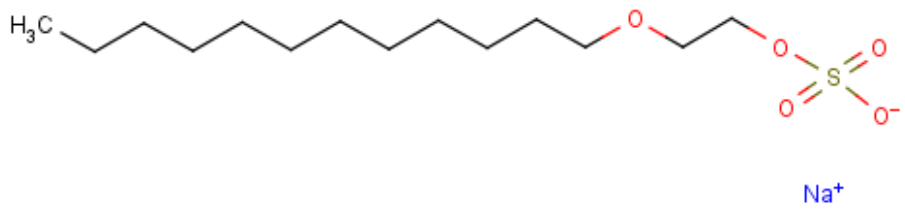
Chemical Identities

Chemical Name in the Inventory and Synonyms	**Ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt** Sodium laureth sulfate Diethylene glycol, monolauryl ether, sodium sulfate Sodium lauryl di(oxyethyl) sulfate Sodium 2-(2-dodecyloxyethoxy)ethyl sulphate Ethanol, 2-[2-(dodecyloxy)ethoxy]-, 1-(hydrogen sulfate), sodium salt (1:1)
CAS Number	3088-31-1
Structural Formula	
Molecular Formula	C16H34O6S.Na
Molecular Weight	376.49

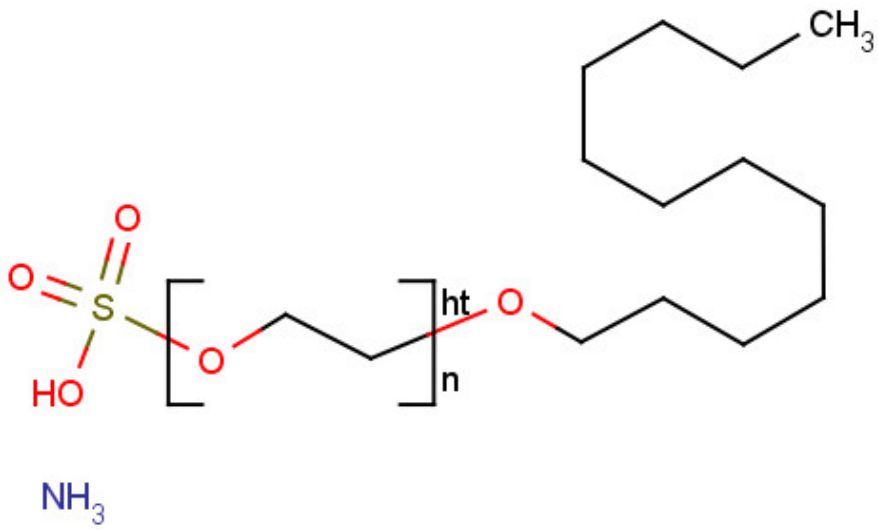
Chemical Name in the Inventory and Synonyms	**Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-(dodecyloxy)-, sodium salt (1:1)** Sodium laureth sulfate Genapol ZRO Polyethylene glycol, sulfate, monododecyl ether, sodium salt Polyoxyethylene, lauryl sulfate, sodium salt Sodium dodecylpolyoxyethylene, sulfate
CAS Number	9004-82-4
Structural Formula	

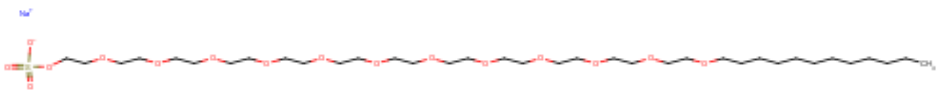
	
Molecular Formula	(C2H4O)nC12H26O4S.Na
Molecular Weight	332.43

Chemical Name in the Inventory and Synonyms	**Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]-, hydrogen sulfate, sodium salt** Sodium laureth sulfate Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]-, 1-(hydrogen sulfate), sodium salt (1:1) Sodium 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]ethyl sulphate Sodium dodeceth-3 sulfate Triethylene glycol dodecyl ether sulfate sodium salt
CAS Number	13150-00-0
Structural Formula	
Molecular Formula	C18H38O7S.Na
Molecular Weight	420.54

Chemical Name in the Inventory and Synonyms	**Ethanol, 2-(dodecyloxy)-, hydrogen sulfate, sodium salt** Sodium laureth sulfate Ethanol, 2-(dodecyloxy)-, 1-(hydrogen sulfate), sodium salt (1:1) Sodium 2-(dodecyloxy)ethyl sulphate 2-(Dodecyloxy)ethanol, hydrogen sulfate sodium salt Ethylene glycol monolauryl ether sulfate sodium salt
CAS Number	15826-16-1
Structural Formula	
Molecular Formula	C14H30O5S.Na
Molecular Weight	332.43

Chemical Name in the Inventory and Synonyms	**Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-(dodecyloxy)-, ammonium salt** Ammonium laureth sulfate Glycols, polyethylene, mono(hydrogen sulfate), dodecyl ether, ammonium salt Polyethylene glycol, monododecyl ether, hydrogen sulfate, ammonium salt Polyoxythylene lauryl, ether ammonium sulfate .alpha.-Sulfo-.omega.-(dodecyloxy)polyoxyethylene, ammonium salt
CAS Number	32612-48-9
Structural Formula	

	
Molecular Formula	(C2H4O)nC12H26O4S.H3N
Molecular Weight	327.48

Chemical Name in the Inventory and Synonyms	**3,6,9,12,15,18,21,24,27,30,33,36-Dodecaoxaoctatetracontan-1-ol, hydrogen sulfate, sodium salt** Sodium laureth sulfate Sodium dodeceth-12 sulfate 3,6,9,12,15,18,21,24,27,30,33,36-Dodecaoxaoctatetracontan-1-ol, 1-(hydrogen sulfate), sodium salt (1:1) Sodium 3,6,9,12,15,18,21,24,27,30,33,36-dodecaoxaoctatetracontyl sulphate Sodium lauryl dodeca(oxyethyl) sulfate
CAS Number	66161-57-7
Structural Formula	
Molecular Formula	C36H74O16S.Na
Molecular Weight	817.01

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