Anionic surfactants with limited data availability: Human health tier II assessment

01 July 2016

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
.beta.-Alanine, N-dodecyl-	1462-54-0
1-Octanesulfonic acid, sodium salt	5324-84-5
Benzenesulfonic acid, oxybis[dodecyl-, disodium salt	25167-32-2
Benzenesulfonic acid, dodecyl(sulfophenoxy)-, disodium salt	28519-02-0
Amines, tallow alkyl, ethoxylated, phosphates	68308-48-5
Glycine, N-(2-hydroxyethyl)-N-[2-[(1-oxododecyl)amino]ethyl]-, monosodium salt	66161-62-4
Glycine, N-(2-hydroxyethyl)-N-[2-[(1-oxooctadecyl)amino]ethyl]-, monosodium salt	68298-17-9
Poly(oxy-1,2-ethanediyl), .alpha.-(3-carboxy-1-oxosulfopropyl)-.omega.-(decyloxy)-, disodium salt	68630-97-7

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 have a surfactant activity and are of variable chemical structures. They are anionic surfactants consisting of aliphatic amines, alkyl sulfonates, and alkyl benzene sulfonates. Based on a review of publicly available hazard information in accordance with the IMAP Framework (NICNAS, 2013), limited or no toxicological data are available for the chemicals in this group.

For chemicals with limited data, NICNAS will commonly use the principles of 'read across' in accordance with the Organisation for Economic Co-operation and Development (OECD) *Guidance on Grouping of Chemicals* (OECD, 2014) based on known properties of similar chemicals (analogues). The quality of the data used depends on how similar the analogues are to the chemicals.

The critical concern for this group of chemicals relates to potential skin and eye irritation. As such, these health hazards will be the focus of this assessment, with other hazards not considered.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified.

International

The following international uses have been identified through Galleria Chemica; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; the US Household Products Database; and the Substances and Preparations in Nordic countries (SPIN) database.

The chemicals have reported cosmetic or domestic uses as surfactants.

The chemicals oxybis(dodecyl benzenesulfonic acid), disodium salt (CAS No. 25167-32-2) and dodecylbenzenesulfonic acid, disodium salt (CAS No. 28519-02-0) have reported commercial use in battery cleaners (concentration not specified) (Household Products Database).

The chemical sodium octyl sulfonate (CAS No. 5324-84-5) has reported site-limited use as an intermediate in the preparation of anti-static polyester fibres (Galleria).

Restrictions

Australian

No known restrictions have been identified.

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

There are limited or no toxicological data available for the chemicals in this group.

The chemicals lauraminopropionic acid (CAS No. 1462-54-0), sodium lauroamphoacetate (CAS No. 66161-62-4), sodium stearoamphoacetate (CAS No. 68298-17-9) and tallow amine, ethoxylated, phosphated (ATAEP) (CAS No. 68308-48-5) are aliphatic, amine-based anionic surfactants. The toxicity of this group of chemicals increases with the length of the carbon chain or with an increased number of amines (US EPA, 2010a). Aliphatic amines are known to be highly irritating to the eyes, skin and mucous membranes (PubChem).

The chemical sodium octyl sulfonate (CAS No. 5324-84-5) is an alkane sulfonate. Health hazard data are read-across from the structurally similar alkyl sulfate and olefin sulfonate anionic surfactant groups. These groups caused skin and eye irritation, but do not show sensitising potential in animal studies. Alkyl sulfates were severely irritating to rabbit eyes at concentrations =10 % and less irritating (mild to moderate) at lower concentrations. A threshold concentration of 20 % for skin irritation was determined for humans when tested with alkyl sulfates (OECD, 2007).

The chemicals oxybis (dodecyl benzenesulfonic acid), disodium salt (CAS No. 25167-32-2) and dodecylphenoxybenzenesulfonic acid, disodium salt (CAS No. 28519-02-0) are categorised as C12 alkyl diphenyl oxide disulfonates (ADPODS) sodium salts by the US Environmental Protection Agency (EPA) High Production Volume (HPV) Challenge Program. The chemicals identified by CAS Nos. 25167-32-2 and 28519-02-0 have been identified as branched and linear C12 alkyl groups, respectively (also known commercially under the CAS Nos. 119345-04-9, and 149119-20-0, which are not listed in the Australian Inventory of Chemical Substances (AICS)). The branched sodium salt (CAS No. 25167-32-2) was moderately irritating to rabbit skin and eyes. The linear sodium salt (CAS No. 28519-02-0) was not irritating to the skin, but irritating to the eyes of rabbits. No other details were provided (US EPA, 2010b).

The chemical disodium decylpolyethylenoxy sulfosuccinate (CAS No. 68630-97-7) is listed on the CosIng database as disodium deceth-5 sulfosuccinate, but under a different CAS number by the Cosmetic Ingredient Review (CIR) Panel. The CIR assessed alkyl PEG sulfosuccinates and noted that the disodium deceth-5 sulfosuccinate was not in current use and, if used in cosmetic formulations, the concentrations and hazard properties will be expected to be equivalent to disodium laureth sulfosuccinate (CIR, 2012).

The main hazard findings for anionic surfactants (linear alkylbenzene sulfonates and sodium, potassium and ammonium sulfates) are eye irritation, which can be severe at high concentrations. At high concentrations, they can also irritate the skin (NICNASa, b).

Risk Characterisation

Critical Health Effects

Based on the limited data available, there is the potential for skin and eye irritation. Other health hazards have not been considered.

Public Risk Characterisation

The public could be exposed to the chemicals in this group if they are used in cosmetic or domestic formulations in Australia. Although use in cosmetic or domestic products in Australia is not known, the chemicals are reported to be used overseas as surfactants (concentrations not specified). The main routes of public exposure are expected to be through the skin and eyes.

Overall, there is sufficient uncertainty regarding the use of these chemicals in cosmetic or domestic products and their safety as used. Therefore, a Tier III assessment may be required (see **NICNAS Recommendation**).

Occupational Risk Characterisation

During product formulation, dermal and ocular exposure may occur, particularly where manual or open processes are used. 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.

Overall, there is sufficient uncertainty regarding the hazards of these chemicals in cosmetic or domestic products to prepare a Tier III assessment (see **NICNAS Recommendation**) to determine the appropriate occupational controls.

NICNAS Recommendation

It is recommended that NICNAS undertake further consultation to determine to what extent these chemicals are used.

Should the consultation identify additional evidence about the use of the chemicals that could pose a risk to workers and/or the public, a Tier III assessment should be undertaken to characterise the risk and make appropriate recommendations if necessary.

Regulatory Control

References

Cosmetic Ingredient Review (CIR) 2012. Final Report on the Safety Assessment of Alkyl PEG Sulfosuccinates as Used in Cosmetics. Accessed April 2015 at http://www.cir-safety.org/sites/default/files/Sulfos032012FR_0.pdf

European Commission Cosmetic Ingredients and Substances (CosIng) Database. Accessed April 2015 at http://ec.europa.eu/consumers/cosmetics/cosing/

Galleria Chemica. Accessed April 2015 at http://jr.chemwatch.net/galeria/

NICNAS 2013. Inventory Multi-tiered Assessment and Priorisation (IMAP) Factsheet 4: Leveraging international information. Accessed April 2015 at http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-factsheets

NICNASa. Inventory Multi-tiered Assessment and Priorisation (IMAP): Human health Tier II assessment for Linear Alkylbenzene Sulfonates (C10-C16). Accessed April 2015 at http://www.nicnas.gov.au

NICNASb. Inventory Multi-tiered Assessment and Priorisation (IMAP): Human health Tier II assessment for Sodium, Ammonium and Potassium Lauryl Sulfate. Accessed April 2015 at http://www.nicnas.gov.au

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 2015 at http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en

OECD Screening Information Dataset (SIDS) 2007. SIDS Initial Assessment Report for Alkyl Sulfates, Alkane Sulfonates and Alpha-Olefin Sulfonates. Accessed June 2016 at http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=EC648443-7268-4557-82DF-7297718B224B

Substances in Preparations in Nordic Countries (SPIN). Accessed April 2015 at http://188.183.47.4/dotnetnuke/Home/tabid/58/Default.aspx

United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary. Accessed April 2015 at http://gov.personalcarecouncil.org/jsp/gov/GovHomePage.jsp

US Environmental Protection Agency (US EPA, 2010a). TSCA New Chemicals Program (NCP) Chemical Categories. Accessed April 2015 at http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf

US Environmental Protection Agency (US EPA, 2010b). Screening-level Hazard Characterization. Alkyl Diphenyl Oxide Disulfonates (ADPODS) Category. Accessed April 2015 at http://www.epa.gov/chemrtk/hpvis/hazchar/Category_ADPODS_September_2010.pdf

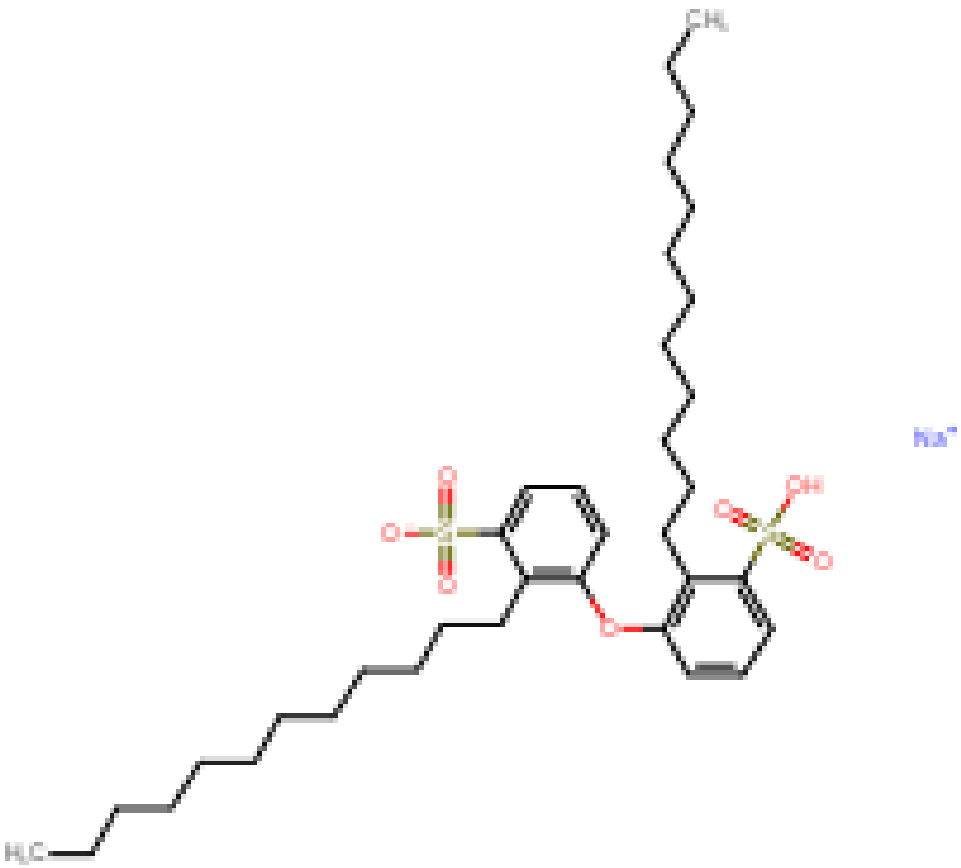
US National Library of Medicines, Household Products Database, Health & Safety Information on Household Products. Accessed April 2015 at http://householdproducts.nlm.nih.gov/
Last Update 01 July 2016

Chemical Identities

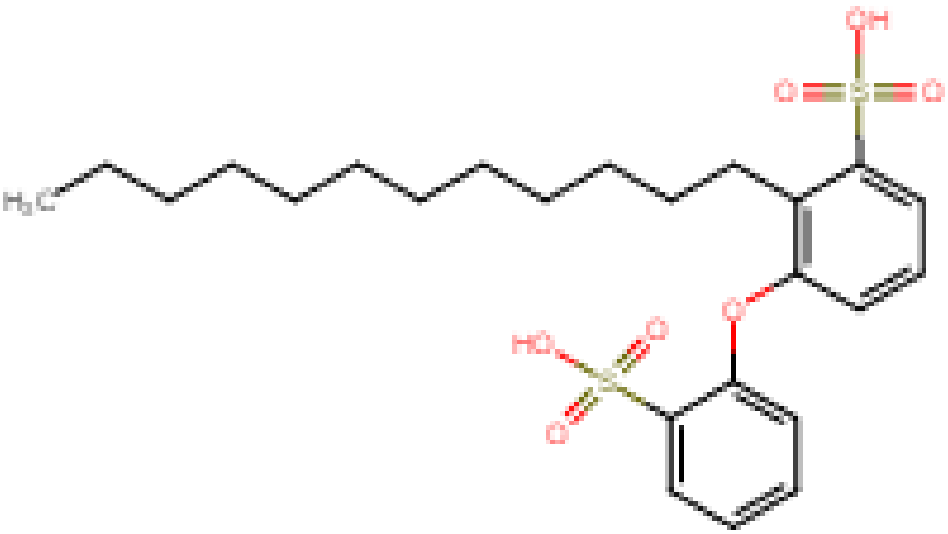
Chemical Name in the Inventory and Synonyms	**.beta.-Alanine, N-dodecyl-** lauraminopropionic acid n-dodecyl-beta-alanine dodecyl(carboxyethyl)amine 3-(dodecylamino)propionic acid n-lauryl-beta-alanine
CAS Number	1462-54-0
Structural Formula	
Molecular Formula	C15H31NO2
Molecular Weight	257.415

Chemical Name in the Inventory and Synonyms	**1-Octanesulfonic acid, sodium salt** sodium octyl sulfonate sodium caprylyl sulfonate
CAS Number	5324-84-5
Structural Formula	
Molecular Formula	C8H18O3S.Na
Molecular Weight	216.275

Chemical Name in the Inventory and Synonyms	**Benzenesulfonic acid, oxybis[dodecyl-, disodium salt** benzenesulfonic acid, 2,2(or 3,3)-oxybis[5(or 2)-dodecyl-, disodium salt disodium oxybis(dodecylbenzenesulfonate) oxybis(dodecyl benzenesulfonic acid), disodium salt
CAS Number	25167-32-2
Structural Formula	

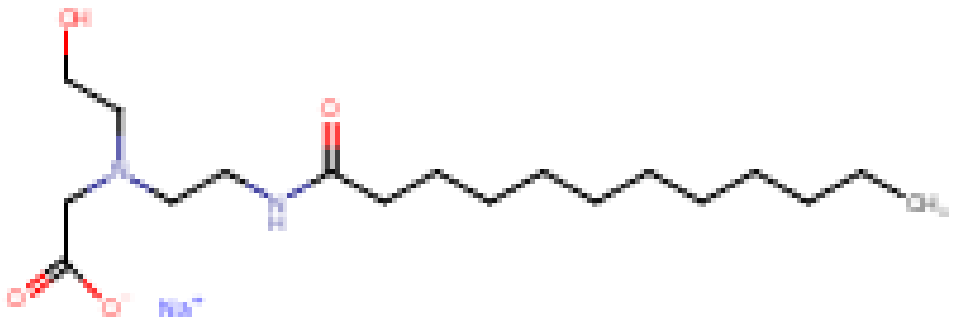
	
Molecular Formula	C36H58O7S2.2Na
Molecular Weight	688.961

Chemical Name in the Inventory and Synonyms	**Benzenesulfonic acid, dodecyl(sulfophenoxy)-, disodium salt** benzenesulfonic acid, dodecyl (sulfophenoxy)-, disodium salt disodium dodecyl(sulphonatophenoxy)benzenesulphonate dodecylphenoxybenzenesulfonic acid, disodium salt
CAS Number	28519-02-0
Structural Formula	

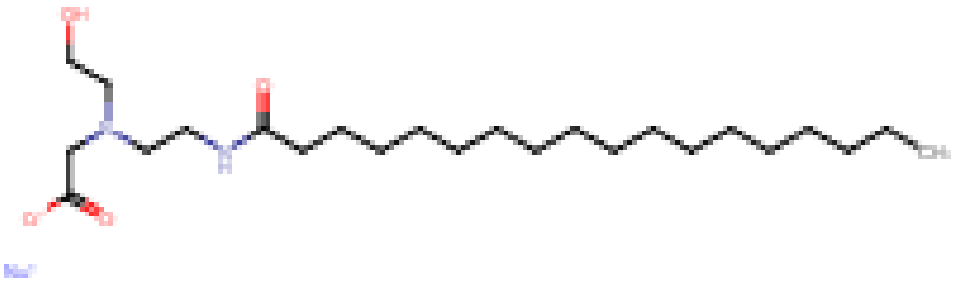
	
Molecular Formula	C24H34O7S2.2Na
Molecular Weight	498.658

Chemical Name in the Inventory and Synonyms	**Amines, tallow alkyl, ethoxylated, phosphates** tallow amine, ethoxylated, phosphated
CAS Number	68308-48-5
Structural Formula	**No Structural Diagram Available**

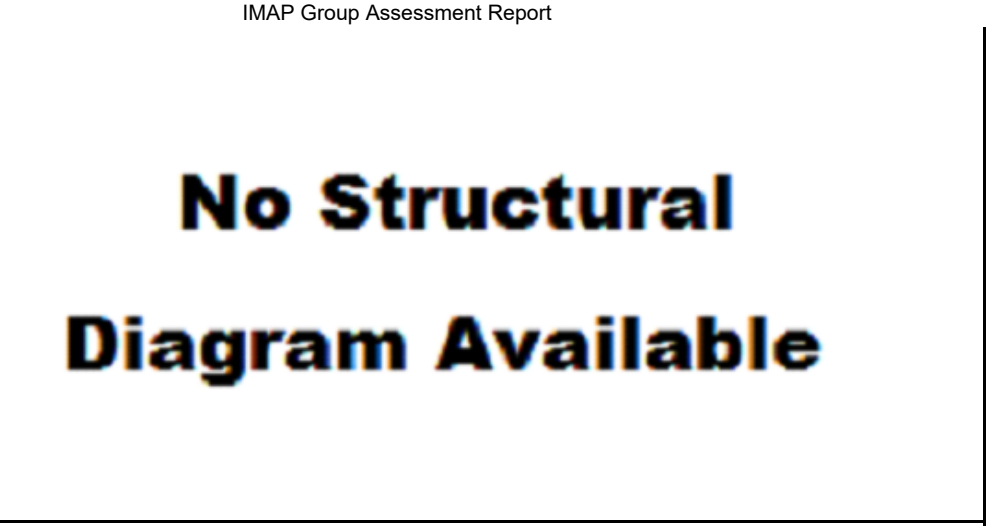
Molecular Formula	Unspecified
Molecular Weight	

Chemical Name in the Inventory and Synonyms	**Glycine, N-(2-hydroxyethyl)-N-[2-[(1-oxododecyl)amino]ethyl]-, monosodium salt** 2-laurylamido-N-hydroxyethyl-N-(sodium carboxymethyl)ethylamine sodium lauroamphoacetate glycine, n-(2-hydroxyethyl)-N-(2-((1-oxododecyl)amino)ethyl)-, monosodium salt
CAS Number	66161-62-4
Structural Formula	
Molecular Formula	C18H36N2O4.Na
Molecular Weight	366.474

Chemical Name in the Inventory and Synonyms	**Glycine, N-(2-hydroxyethyl)-N-[2-[(1-oxooctadecyl)amino]ethyl]-, monosodium salt** aminoacetic acid, N-2-hydroxyethyl-N-[2-(octadecylamido)ethyl

	sodium N-(2-hydroxyethyl)-N-(2-((1-oxooctadecyl)amino)ethyl)glycinate sodium stearoamphoacetate
CAS Number	68298-17-9
Structural Formula	
Molecular Formula	C24H48N2O4.Na
Molecular Weight	450.635

Chemical Name in the Inventory and Synonyms	**Poly(oxy-1,2-ethanediyl), .alpha.-(3-carboxy-1-oxosulfopropyl)-.omega.-(decyloxy)-, disodium salt** disodium decylpolyethylenoxy sulfosuccinate poly(oxy-1,2-ethanediyl), alpha-(3-carboxy-1-oxosulfopropyl)-omega-(decyloxy)-, disodium salt disodium deceth-5 sulfosuccinate
CAS Number	68630-97-7
Structural Formula	

	
Molecular Formula	(C2H4O)nC14H26O7S.2Na
Molecular Weight	

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