Sodium, ammonium and potassium lauryl sulfate: Human health tier II assessment

28 June 2013

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

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Sulfuric acid, monododecyl ester, sodium salt	151-21-3
Sulfuric acid, monododecyl ester, ammonium salt	2235-54-3
Sulfuric acid, monododecyl ester, potassium salt	4706-78-9

Preface

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

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

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

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

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



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

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

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

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

Disclaimer

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

ACRONYMS & ABBREVIATIONS

Grouping Rationale

Members of this group contain the common structural feature of a predominantly linear aliphatic hydrocarbon chain (C₁₂) with an anionic sulphate group, neutralised with a counterion (i.e., Na⁺, K⁺, NH⁴⁺). The presence of an aliphatic hydrocarbon chain and the polar sulfate group confer surfactant properties and enable the commercial use of these substances as anionic surfactants (OECD, 2007). The cations in each case have very low systemic toxicity (NICNAS, 2013).

Even though the physical-chemical behaviour of these chemicals may be influenced by different counterions, they are not expected to affect the chemical reactivity and the hazard classification for the purpose of this assessment.

Given the close structural similarities and surfactant properties of the chemicals of this group, identical hazard profiles for human health are expected. The chemicals of this group also have similar reported uses.

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information for sodium lauryl sulfate (CAS No. 151-21-3) and ammonium lauryl sulfate (CAS No. 2235-54-3).

The chemicals have reported cosmetic use as cleansing, emulsifying, foaming, wetting and dispersing agents.

The chemicals have reported domestic use as surface-active agents for their properties including:

- foaming, wetting, dispersing, emulsifying properties; and
- emulsion polymerisation in detergents.

The chemicals have reported commercial use:

as surface-active agents with foaming, wetting, dispersing and emulsifying properties; and

• in tanning agents.

No specific Australian use, import, or manufacture information has been identified for potassium lauryl sulfate (CAS No. 4706-78-9).

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), 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 the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

Most chemicals in this group have the following reported general uses as surface-active agents for cosmetic uses including:

- emulsifying, foaming, wetting, cleansing and denaturants; and
- emulsion polymerisation, detergents and shampoos.

Most chemicals in this group have the following reported domestic uses as surface-active agents including:

- in household detergents, principally laundry detergents, dishwashing products and household cleaning; and
- foaming, wetting, dispersing and emulsifying properties.

Most chemicals of this group have the following reported commercial uses as surface-active agents including:

- in wool-washing agents and as active ingredients in both light- and heavy-duty laundry formulations (upholstery formulations);
- as an emulsifier and penetrant in varnish and paint remover;
- in impregnation materials, fillers, construction materials; and
- in cleaning/washing agents, adhesives, binding agents, detergent, and in emulsion polymerisation in metal processing.

The following non-industrial uses have also been identified:

- as an emulsifier, whipping agent and surfactant in foods;
- as an emulsifier, wetting agent and adjuvant in insecticides;
- as non-agricultural pesticides and preservatives; and
- in the preparation of blood samples for red blood cell counts.

In addition, sodium lauryl sulfate (CAS No. 151-21-3) also has the following reported specific commercial uses including:

- as an anti-foaming agent in solid rocket propellants;
- in the electroplating industry (particularly nickel and zinc);
- in the formulation of injection-moulded explosives; and
- laboratory reagents.

Restrictions

Australian

Sodium lauryl sulfate (CAS No. 151-21-3) is listed in The Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, 2012)) in Schedule 6 as follows:

SODIUM LAURYL SULFATE (excluding its salts and derivatives) except:

(a) in wash-off preparations containing 30 per cent or less of sodium lauryl sulfate and, if containing more than 5 per cent of sodium lauryl sulfate, when labelled with a warning to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER;

(b) in leave-on preparations containing 1.5 per cent or less of sodium lauryl sulfate;

(c) in toothpaste and oral hygiene preparations containing 5 per cent or less of sodium lauryl sulfate;

(d) in other preparations for animal use containing 2 per cent or less of sodium lauryl sulfate; or

(e) in other preparations containing 30 per cent or less of sodium lauryl sulfate and, if containing more than 5 per cent of sodium lauryl sulfate, when labelled with warnings to the following effect:

IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and

IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label.

International

No known restrictions have been identified.

Existing Worker Health and Safety Controls

Hazard Classification

Sodium lauryl sulphate (CAS No. 151-21-3) is classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Xn; R21/22 (Acute toxicity)

Xi; R37/38/41 (Irritation)

The other two chemicals in the group are not classified on HSIS.

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemical):

Sodium lauryl sulfate (CAS No. 151-21-3) has an exposure standard of 5–10 mg/m³ time weighted average (TWA) in countries such as Canada, Ireland, Spain, and the USA.

Health Hazard Information

Toxicokinetics

Although specific toxicokinetic information about this group of chemicals is limited, these chemicals are generally well absorbed in the gastrointestinal tract. Maximal concentration was reached within 30 minutes to two hours of oral administration in dogs and humans, indicating rapid absorption. The plasma concentration declined rapidly afterwards and reached 10 % of the maximum concentration after six hours, indicating rapid elimination. After absorption, these chemicals are mainly distributed in the liver and kidney (OECD, 2007; REACH).

As anionic surfactants tend to bind to the skin surface, absorption by the percutaneous route is limited. In guinea pigs, the dermal penetration of ¹⁴C-labelled sodium lauryl sulfate amounted to 0.35 % of the applied dose of 3 µmol. In this study, after 10 minutes of rubbing the treated areas with the chemical, the treated area was washed with water, and then covered with non-occlusive patches for 24 hours (OECD, 2007; REACH).

A significant amount of the absorbed chemical is excreted in the urine—up to 98 % of the dose administered has been reported to be excreted in the urine for sodium lauryl sulfate (CAS No. 151-21-3). There are no major differences in overall excretion between male and female rats after administration by oral, intravenous or intraperitoneal routes (OECD, 2007; REACH).

Acute Toxicity

Oral

The chemicals in this group are of moderate acute oral toxicity.

Sodium lauryl sulfate (CAS No. 151-21-3) is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). The reported oral median lethal dose (LD50) in rats for sodium lauryl sulfate (CAS No. 151-21-3) was 977–1427 mg/kg bw and for ammonium lauryl sulfate (CAS No. 2235-54-3), >135 mg/kg bw. Reported clinical signs included diarrhoea, reduced activity, laboured breathing, hunched posture, coma, and death (OECD, 2007; REACH).

Dermal

One member in this group, sodium lauryl sulfate (CAS No. 151-21-3) is classified as hazardous with the risk phrase 'Harmful in contact with skin' (Xn; R21) in HSIS (Safe Work Australia). While the available data do not support this classification, in the absence of more comprehensive information, the available data are not sufficient to recommend amendment of the current HSIS classification.

The acute dermal LD50 value for sodium lauryl sulfate (CAS No. 151-21-3) was determined to be approximately 200 mg/kg bw in rabbits (OECD, 2007). Clinical signs observed were tremors, tonic-clonic convulsions, respiratory failure, and the terminal skin appearance varied from slight scaling to leathery. Limited information was available about this study. However, considering limited dermal absorption (see **Toxicokinetics**) and the irritant property of this chemical, it is more likely that the observed mortalities in this study were due to the secondary consequence of local effects, not systemic effects.

Inhalation

No data are available.

Corrosion / Irritation

Respiratory Irritation

The chemicals in this group are respiratory irritants.

One member of this group, sodium lauryl sulfate (CAS No. 151-21-3), is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (Safe Work Australia). The available human data support this classification (see **Observation in humans**).

Skin Irritation

The chemicals in this group are skin irritants.

One member of this group, sodium lauryl sulfate (CAS No. 151-21-3) is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The available data support this classification (OECD, 2007; NICNAS, 2007).

Sodium lauryl sulfate (CAS No. 151-21-3) has been found to be irritating to the skin of rabbits, producing erythema and oedema on unabraded rabbit skin after a four-hour application of a 5–25 % solution (OECD, 2007).

Eye Irritation

The chemicals in this group are severe eye irritants.

One member of this group, sodium lauryl sulfate (CAS No. 151-21-3), is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). The available data support this classification. When treated with a 25 % sodium lauryl sulfate aqueous solution, the irritant effects on rabbit eyes were not reversible within the observation period of 21 days (OECD, 2007; REACH).

Ammonium lauryl sulfate (CAS No. 2235-54-3) was also found to be irritating to rabbit eyes at 10 % and 20 % concentrations, but not at 2 % concentration (NICNAS, 2003; OECD, 2007). No data are available on potassium lauryl sulfate (CAS No. 4706-78-9).

Observation in humans

Skin irritation has been observed in clinical studies in humans with sodium lauryl sulfate (CAS No. 151-21-3). Sodium lauryl sulfate and ammonium lauryl sulfate (CAS No. 2235-54-3) have been reported to be irritants following patch testing at concentrations of ≥ 2 %. The irritation increases with the increasing concentration and longer these chemicals stay in contact with the skin (CIR, 1983). Sodium lauryl sulfate and ammonium lauryl sulfate have been reported to produce a drying effect on skin.

Sodium lauryl sulfate is reported to irritate the respiratory tract and oral mucosa, especially in individuals predisposed to recurrent mouth ulcers (OECD, 2007; NICNAS, 2007).

Sodium lauryl sulfate has also been reported to be the most common cause of eye irritation by commercial shampoos (HSDB, 2013).

Sensitisation

Skin Sensitisation

The chemicals in this group are not skin sensitisers (OECD, 2007; NICNAS, 2003; NICNAS, 2007; REACH).

Although sodium lauryl sulfate (CAS No. 151-21-3) gave positive reactions (induced an increase in cell proliferation) in two out of three local lymph node assays (LLNA), the observed positive reactions were stated to be due to a non-antigen-specific proliferative stimulus induced by the irritating effect of the tested concentrations (4, 5, 10 or 25 %) (OECD, 2007). It is noted that the OECD methodology for guinea pig skin sensitisation predictive tests requires application of 10 % sodium lauryl sulfate at induction, to create local irritation for those test materials with no skin irritation potential. This demonstrates that sodium lauryl sulfate is not considered a skin sensitiser; otherwise there would be concerns over potential cross sensitisation reactions at challenge with the test material (NICNAS, 2007).

There is no information available to indicate that ammonium lauryl sulfate (CAS No. 2235-54-3) is a skin sensitiser (NICNAS, 2003).

Observation in humans

The chemicals in this group have been reported not to be skin sensitisers in humans (OECD, 2007; NICNAS, 2003; NICNAS, 2007).

In a repeat insult patch test, ammonium lauryl sulfate tested negative in 98 volunteers at a concentration of 4 %. While reviewing the cases of contact sensitisation to sodium lauryl sulfate (CAS No. 151-21-3), it was concluded that the chemical is a skin irritant but is not usually a sensitiser. Under conditions of compromised skin, or in the presence of other sensitising agents, a few positive skin sensitisation reactions could be seen with this chemical. Given the widespread use of these chemicals in consumer products, the very low incidence of reported cases indicates that the sensitising potential of chemicals in this group is very low (OECD, 2007).

Repeated Dose Toxicity

Oral

Based on the data available, the chemicals in this group are not considered to cause serious damage to health through repeated oral exposure. A no observable adverse effect level (NOAEL) of approximately 100 mg/kg bw/day, based on various repeated dose toxicity studies, can be established for this group of chemicals (OECD, 2007; NICNAS, 2007).

Gastrointestinal irritation was the primary effect observed after gavage administration, but not after dietary feeding. This is consistent with the primary irritant properties of chemicals in this group (OECD, 2007; NICNAS, 2007). The liver was the only target organ identified following dietary administration. Adverse effects for this organ included an increase in liver weight, enlargement of liver cells, and elevated levels of liver enzymes (OECD, 2007).

In a 28-day gavage study in rats, sodium lauryl sulfate (CAS No. 151-21-3) was administered at dose levels of 30, 100 or 300–600 mg/kg bw/day (the dose of 300 mg/kg bw/day was changed to 600 mg/kg bw/day after 10 days of treatment). In the highest dose group, two animals died. Other observations included increased water intake; decreased food consumption (males only); reduced body weight gain (males only); increased relative weights of adrenals, kidneys, brain, gonads and liver; and decreased relative thymus weight. Histopathological examination revealed ulceration and bleeding in the stomach and compound related transient alterations of the tongue and myocardium. At the middle dose, there were no test-compound related alterations of internal organs. The tongue and myocardium damage was considered to be fully reversible after a recovery period of 29 days; the damage to the forestomach mucosa was partially reversible. No treatment-related systemic effects were observed in the low and mid-dose test groups. A NOAEL of 90 mg/kg bw/day (corresponding to 90 % active substance) and a lowest observed adverse effect level (LOAEL) of 270–540 mg/kg bw/day (corresponding to 90 % active substance) were determined from this study (OECD, 2007; REACH).

In a 90-day feeding study in rats, sodium lauryl sulfate was fed at levels of 40, 200, 1000 or 5000 ppm (corresponding to 3, 17, 86 or 430 mg/kg bw/day). The only effect observed at the highest dose (5000 ppm) was increased liver weight in female animals, without any histopathological changes. As this effect was not considered to be adverse, the NOAEL was established as >5000 ppm (i.e. >430 mg/kg bw/day) (REACH).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Chemicals in this group are not genotoxic in both in vitro and in vivo studies.

One member of this group, sodium lauryl sulfate (CAS No. 151-21-3), has been reported to be not mutagenic in bacterial reverse mutation assays (OECD TG 471), with and without metabolic activation (OECD, 2007; REACH). This chemical has also been reported as being not mutagenic in a mouse lymphoma cell forward mutation assay (OECD TG 476) conducted using mouse lymphoma cell L5178Y tk+/tk-, with and without metabolic activation (OECD, 2007; REACH).

In a chromosome aberration assay, sodium lauryl sulfate was fed to rats (six animals/group) at 0, 500 or 1000 mg/kg bw/day for 90 days. The positive control group was fed the standard diet containing the chemical plus 25 mg/kg bw cyclophosphamide administered intraperitoneally (i.p.) at 20 or 24 hours before termination of the study. Samples were taken at the end of the study and two hours after i.p. injection of 4 mg/kg bw colchicine as mitotic inhibitor. Chromosome preparations were made from bone marrow (femur) of eight animals per day over several days. The chemical had no effect on structural chromosomal aberration as there were no increases in rearrangements, chromatid gaps and breaks, or isochromatid gaps and breaks, in the treatment group (OECD, 2007).

In a dominant lethal study using mice (OECD TG 478), sodium lauryl sulfate had no adverse effects on pregnancy frequency, number of implantations or frequency of early deaths (OECD, 2007).

Carcinogenicity

In the only carcinogenicity study available, sodium lauryl sulfate (CAS No. 151-21-3) was not carcinogenic in beagle dogs, although the short study duration, and limited details provided, limit the significance that can be attached to the data (NICNAS, 2007).

Reproductive and Developmental Toxicity

Reproductive toxicity effects were not observed and developmental effects were a secondary non-specific consequence of severe maternal toxicity. Therefore, the chemicals in this group do not show specific reproductive or developmental toxicity.

The effect on reproductive functions was studied using sodium lauryl sulfate (CAS No. 151-21-3). In this study, groups of 10 male Swiss albino mice were fed sodium lauryl sulfate either at 1 % (corresponds to 1000 mg/kg bw/day) for two weeks or with 0.1 % for six weeks (corresponds to 100 mg/kg bw/day). Animals from each group were mated with females (replaced weekly for three weeks) after one, two or three weeks after dosing. While the body weights were significantly decreased at the highest dose level, there was no impairment of epididymal spermatozoa. It was concluded that sodium lauryl sulfate has no adverse effect on fertility, even when administered at concentrations sufficient to cause a significant reduction in body weight (parental toxicity). A NOAEL of 1000 mg/kg bw/day can be derived for fertility effects in males (OECD, 2007).

In a developmental toxicity study using female Wistar rats, sodium lauryl sulfate (CAS No. 151-21-3) was administered by oral gavage to 15 animals/dose at 0, 63, 125, 250 or 500 mg/kg bw/day, on days 6–15 of gestation (OECD, 2007). Maternal toxicity was observed at the highest dose of 500 mg/kg bw/day. Animals at this dose had diarrhoea, reduced food consumption, reduced maternal body weight gain, and mortality (5/15 died due to gastrointestinal irritation, diffuse haemorrhage of the stomach and congestion of the lungs). There were no signs of developmental toxicity noted at the highest dose of 500 mg/kg bw/day. The NOAELs for maternal and developmental toxicity were reported to be 250 and >500 mg/kg bw/day, respectively.

In another developmental toxicity study (OECD TG 414) with sodium lauryl sulfate using female CD rats, there were no signs of developmental toxicity up to the highest dose of 600 mg/kg bw/day (OECD, 2007; REACH). The chemical was administered by oral gavage at 0, 0.2, 2, 300 or 600 mg/kg bw/day, on days 6–15 of gestation. Maternal toxicity was observed at 300 mg/kg bw/day and above and consisted of anorexia, weight loss, cachexia, abortion, and deaths (3/20) at the highest dose. The NOAELs for maternal and developmental toxicity were reported to be 2 and 600 mg/kg bw/day (highest dose), respectively. The maternal NOAEL derived in this study is of little applicability due to the use of unusual dose spacing.

In developmental toxicity studies in mice (CD-1) and rabbits (New Zealand White), sodium lauryl sulfate (CAS No. 151-21-3) was administered by oral gavage at doses of 0, 0.2, 2, 300 or 600 mg/kg bw/day (OECD, 2007; REACH). There were maternal deaths at 300 (1/20 mice and 1/13 rabbits) and 600 (4/20 mice and 11/13 rabbits) mg/kg bw/day. In rabbits, diarrhoea, anorexia, weight loss, cachexia, and foetal loss were also noted at and above 300 mg/kg bw/day. There were no adverse effects on foetal morphogenesis in either species at and up to 300 mg/kg bw/day. However, there was total resorption and/or increased incidence of litter loss at 600 mg/kg bw/day in both species. The NOAELs for maternal and developmental toxicity were reported to be 2 and 300 mg/kg bw/day, respectively, for both species. The maternal NOAEL derived in this study is of little applicability due to the use of unusual dose spacing.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are systemic acute effects (acute toxicity by oral and dermal routes of exposure) and local effects (skin irritation, respiratory irritation, and the possibility of causing serious damage to eyes).

Public Risk Characterisation

Sodium lauryl sulfate (CAS No. 151-21-3) and ammonium lauryl sulfate (CAS No. 2235-54-3) have reported cosmetic and domestic uses in Australia. While no specific Australian use was identified for potassium lauryl sulfate (CAS No. 4706-78-9), the chemical is known to be used overseas in cosmetics.

One member in this group (sodium lauryl sulfate) is currently listed on Schedule 6 of the SUSMP. Strong warning statements, safety directions and first aid instructions apply to any cosmetic or domestic products containing the chemical. The current controls are considered adequate to minimise the risk to public health posed by the known uses of this chemical in cosmetic or domestic products. Therefore, the risk to public health is not considered to be unreasonable for this chemical under all normal circumstances of use, apart from if the chemical is used in laundry detergent capsules.

Considering the critical health effects and a similar use pattern to sodium lauryl sulfate, in the absence of any regulatory controls similar to sodium lauryl sulphate; ammonium lauryl sulfate (CAS No. 2235-54-3) and potassium lauryl sulfate (CAS No. 4706-78-9) also have the potential to pose an unreasonable risk under the uses identified.

Liquid laundry detergent capsules, which rapidly dissolve in contact with moisture, have been reported to cause 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 are 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, 2013).

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the 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 the chemicals at lower concentrations may also occur while using formulated products containing the chemical. 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, the chemicals in this group may pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemicals are implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer), has adequate information to determine appropriate controls. The data available support the hazard classification of ammonium lauryl sulfate (CAS No. 2235-54-3) and potassium lauryl sulfate (CAS No. 4706-78-9) (see **Recommendation section**).

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of ammonium lauryl sulfate (CAS No. 2235-54-3) and potassium lauryl sulfate (CAS No. 4706-78-9) in cosmetics and domestic products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through changes to classification and labelling.

Assessment of the chemical is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Public Health

It is recommended that an amendment to the current listing of sodium lauryl sulfate (CAS No. 151-21-3) in the SUSMP be considered to include the other two chemicals in this group given the same critical health effects and similar use pattern.

Work Health and Safety

The chemicals in this group are recommended for classification and labelling under the current approved criteria and adopted 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 in contact with skin (Xn; R21)*	Harmful if swallowed - Cat. 4 (H302) Harmful in contact with skin - Cat. 4 (H312)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)* Irritating to skin (Xi; R38)* Irritating to respiratory system (Xi; R37)*	Causes serious eye damage - Cat. 1 (H318) Causes skin irritation - Cat. 2 (H315) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)

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

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

* Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemicals in this group 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 ACCC'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, ocular, and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals*— *Code of Practice* and *Labelling of Workplace Hazardous Chemicals*—*Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

References

Accord 2013. Accord statement on 'Laundry industry responds to ACCC's alert on the safe storage and handling of liquid capsules'. Accessed June 2013 at

http://www.accord.asn.au/members/resources/submissions/accord_public_statements/accord_statement_on_liquid_lau

Australian Competition & Consumer Commission (ACCC). ACCC warns consumers about liquid laundry detergent capsule injuries – Date 6 February 2013. Accessed 14 June 2013 at http://www.productsafety.gov.au/content/index.phtml/itemId/998779/fromItemId/998653

ChemIDPlus Advanced. Accessed April 2013 at http://chem.sis.nlm.nih.gov/chemidplus/

Cosmetic Ingredient Review 1983. Final Report on the Safety Assessment of Sodium lauryl sulphate and ammonium lauryl sulfate. Journal of the American College of Toxicology, Volume 2, Number 7, 127-181

Galleria Chemica. Accessed April 2013 at http://jr.chemwatch.net/galleria/

Hazardous Substances Data Bank (HSDB). National Library of Medicine. Accessed on April 2013 at http://toxnet.nlm.nih.gov.

NICNAS 2003. NICNAS Existing Chemicals Information Sheet: Ammonium Lauryl Sulfate. Accessed May 2013 at http://www.nicnas.gov.au/publications/information_sheets/existing_chemical_information_sheets/ammonium_lauryl_sulfate_april_2003.pdf.

NICNAS 2007. NICNAS Existing Chemicals Information Sheet: Sodium Lauryl Sulfate. Accessed April 2013 at http://www.nicnas.gov.au/publications/information_sheets/existing_chemical_information_sheets/sodium_lauryl_sulfate_october_2007.pdf.

NICNAS 2013. IMAP Assessments - Identification of chemicals of low concern to human health. Accessed June 2013 at http://nicnas.gov.au/Industry/Existing_Chemicals/Chemicals_On_AICS/IMAP_Framework/Identification%20of%20Chemicals%20of% 20Low%20Concern%20to%20human%20health.pdf

OECD 2007. SIAR on category of Alkyl sulfates, Alkane sulfonates and a-Olefin sulfonates. Accessed April 2013 at http://webnet.oecd.org/hpv/UI/SIDS_Details.aspx?Key=d796277d-731b-4839-a21d-e22296ecc80a&idx=0 OECD, 2007

REACH Dossier. Bis(2-ethylhexyl) adipate (103-23-1). Accessed April 2013 at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

REACH Dossier. Sodium dodecyl sulphate (151-21-3). Accessed April 2013 at http://echa.europa.eu/web/guest/information-onchemicals/registered-substances

Safe Work Australia (SWA). Hazardous Substances Information system (HSIS). Accessed April 2013 at http://hsis.safeworkaustralia.gov.au/HazardousSubstance.

Substances in Preparations in Nordic Countries (SPIN). Accessed April 2013 at http://188.183.47.4/dotnetnuke/Home/tabid/58/Default.aspx

The Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) 2012. Accessed April 2013 at http://www.comlaw.gov.au/Details/F2012L01200/Download. Last Update 28 June 2013

Chemical Identities

Chemical Name in the Inventory and Synonyms	Sulfuric acid, monododecyl ester, sodium salt Sodium lauryl sulfate Sodium dodecyl sulfate Sulfuric acid, monododecyl ester, sodium salt Lauryl sodium sulfate Sodium N-dodecyl sulfate
CAS Number	151-21-3
Structural Formula	H ₃ C
Molecular Formula	C12H26O4S.Na
Molecular Weight	288.38

Chemical Name in the Inventory and Synonyms	Sulfuric acid, monododecyl ester, ammonium salt Ammonium lauryl sulfate Ammonium dodecyl sulphate Dodecyl ammonium sulfate Sulfuric acid, monododecyl ester, ammonium salt Lauryl ammonium sulfate
CAS Number	2235-54-3
Structural Formula	



Molecular Formula	C12H26O4S.H3N
Molecular Weight	283.43
	203.43

Chemical Name in the Inventory and Synonyms	Sulfuric acid, monododecyl ester, potassium salt Potassium dodecyl sulfate Potassium lauryl sulfate Dodecyl sulfate, potassium salt Sulfuric acid, monododecyl ester, potassium salt (1:1)
CAS Number	4706-78-9
Structural Formula	



Share this page