Selected anionic surfactants: Human health tier II assessment

03 July 2015

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts	68439-57-6
Sulfuric acid, mono-C12-18-alkyl esters, sodium salts	68955-19-1

Preface

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

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

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

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

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

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

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

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

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

This group of chemicals [sodium a-olefin sulfonate (sodium AOS; CAS No 68439-57-6) and sodium alkyl sulfate (sodium AS; CAS No 68955-19-1)] are anionic surfactants that are manufactured by sulfoxidation of n-paraffins (HERA, 2002). The chemicals in this group contain the common structural feature of a predominantly linear aliphatic hydrocarbon chain with a polar sulfate or sulfonate group, with a sodium counterion. The hydrocarbon chain (with a length between C12 and C18) and the presence of the polar sulfate or sulfonate groups give the surfactant the chemicals' properties and enable them to be used commercially as anionic surfactants (OECD, 2007; NICNASa; NICNASb).

The cation is 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 this group of chemicals, identical hazard profiles for human health are expected. These chemicals 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 this group of chemicals.

The chemicals have reported cosmetic uses:

- in soaps;
- in hair shampoos;

- in shower gels; and
- as foaming, cleansing, emulsifying and surfactant agents.

The chemicals have reported domestic uses, including:

- in adhesive and binding agents; and
- as surface-active agents in household/laundry detergents.

The chemicals have reported commercial uses, including:

- in the leather tanning industry;
- in frothers;
- in chemical and physical blowing agents;
- in bleaching agents;
- in dry cleaning solvents;
- in optical brighteners in detergents;
- in condensation removers;
- in dust binding agents; and
- as anti-set-off agents.

International

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

The following uses are also reported in various international assessments including: Human and Environmental Risk Assessment (HERA) on ingredients of European household cleaning products (HERA, 2002) and the OECD Screening information data set International Assessment Report (SIAR) (OECD, 2007).

The chemicals have reported cosmetic uses (maximum concentration) in:

- shampoos (16 %);
- bath and shower products;
- facial cleansing foams (3.6 %);
- skin care preparations (>5–10 %);
- personal hygiene products (>10 %);
- leave-on products;
- rinse-off products;

- bubble baths (10 %); and
- emulsions and toothpastes.

The chemicals have reported domestic uses as surface-active agents including in:

- household detergents (maximum 16.5 %);
- laundry detergents;
- dishwashing products;
- household cleaning products; and
- hand dishwashing liquid.

The chemicals have reported commercial uses including:

- in emulsion polymerisation;
- in fire-fighting foams;
- as wool-washing agents;
- as active ingredients in both light and heavy duty laundry formulations;
- as emulsifiers in printing ink manufacture; and
- in construction materials.

The chemicals have reported site-limited use in metal surface treatment products.

The chemicals have reported non-industrial uses including:

- as an emulsifier, wetting agent and adjuvant in insecticides;
- in non-agricultural pesticides; and
- in froth flotation for pharmaceutical applications.

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

Toxicokinetics

When radiolabelled sodium a-olefin sulfonate (^{14}C- sodium AOS) was administered as a single dose of 100 mg (50 µCi)/kg to Wistar rats by gavage, the chemical was rapidly absorbed from the gastrointestinal tract (GIT) and readily metabolised and excreted in the urine. Approximately 80 % of the administered dose was absorbed in the GIT. Blood concentrations peaked at three hours after dosing, and by 24 hours, 72 % of the absorbed dose had been excreted in the urine (Inoue, O'Grodnick and Tomizawa, 1982; HERA, 2002).

Similar results were obtained from studies using alkyl sulfates in rats, pigs and humans. Peak plasma concentrations were reported between 30 minutes and 2 hours after oral administration in dogs and humans, indicating rapid absorption. Urine excretion ranging from 80 % to 90 % of the dose administered in rats, pigs and humans, irrespective of the chemical's chain length and counter ion, has been reported (HERA, 2002; OECD, 2007).

Parenteral administration of ^{14}C-sodium AOS at a single dose of 10 mg (5 µCi)/kg in Wistar rats resulted in rapid absorption and excretion. After absorption, ^{14}C-sodium AOS was found to be mainly distributed in the liver, intestine, kidneys and blood. Half of the dose administered was excreted in the urine within an hour of dosing, and 90 % was excreted by six hours (Inoue, O'Grodnick and Tomizawa, 1982; HERA, 2002).

Percutaneous absorption is limited as anionic surfactants tend to bind to the skin surface. When 0.5 mL of 0.2 % ^{14}C-sodium AOS in an aqueous solution was applied on the intact skin of rats, 60 % to 70 % of the applied dose was recovered from the cotton balls used to remove the radioactive isotope from the application site. Dermal absorption was estimated to be 0.6 % of the applied dose. Around 24 hours after application, 0.33 %, 0.21 % and 0.08 % of the applied dose was recovered from the urine, main organs and bile, respectively (HERA, 2002; OECD, 2007; REACHa).

The available studies indicate that the chemicals in this group are extensively metabolised in rats, dogs and humans. The metabolic degradation of these chemicals is initiated by cytochrome P450-dependent ?-oxidation followed by β-oxidation of the aliphatic fatty acids. The major metabolites identified are sulfate esters or sulfonic acids with chain lengths of C2 or C4. The metabolites are rapidly excreted in the urine (HERA, 2002; OECD, 2007; REACH).

Acute Toxicity

Oral

The chemicals in this group have low to moderate acute toxicity, based on results from animal tests following oral exposure. The median lethal doses (LD50) ranged from 1.4 to 7.8 g/kg (1400 to 7800 mg/kg) in rats and 2.6 to >8 g/kg (2600 to 8000 mg/kg) in mice (HERA, 2002; OECD 2007; REACHa).

Mortality was reported in animals following acute oral exposure to the chemicals at concentrations ranging from 1807 to 4000 mg/kg bw. Clinical observations included impaired gastrointestinal tract, stomach tightly filled with brownish fluid and foam, dark-red content of the gastric mucosa and the colon, and minor petechial bleeding in the lung.

Dermal

The chemicals in this group have low dermal toxicity, based on results from animal tests following acute dermal exposure. The LD50 for sodium AOS was reported to be >6000 mg/kg bw in rabbits (HERA, 2002; OECD, 2007; REACHa).

No data were available on dermal toxicity for sodium alkyl sulfate. However, it is expected that AS will have low dermal toxicity based on similarities in physico-chemical properties and toxicokinetics with sodium AOS and sodium lauryl sulfate (SLS; CAS No. 151-21-3) (NICNAS a).

Inhalation

Based on the available information for sodium AOS, the chemicals in this group have low acute toxicity following inhalation exposure.

In an acute inhalation toxicity study similar to OECD Test Guideline (TG) 403, rats (unknown strain) (10 animals/dose) were exposed to 90 % of sodium AOS as a powdered aerosol for one hour. Clinical observations were made for up to 14 days post administration. No mortalities were reported and the median lethal concentration (LC50) was reported to be >229 mg/L (equivalent to >52 mg/L for a four-hour exposure of the undiluted chemical) (REACHa).

Corrosion / Irritation

Skin Irritation

Based on the available information, the chemicals in this group are considered skin irritants warranting hazard classification. Data on SLS are also provided as read across, since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

In a skin irritation study conducted on six New Zealand White rabbits, 0.5 mL of sodium AOS solution (38 % active) was applied dermally to shaved, intact and abraded skin for 24 hours under occlusion. The treated site was not washed after the test substance was removed. Very slight irritation was observed on intact skin in 5/6 animals. One of the six animals had well-defined erythema, which had completely reversed by 72 hours after dosing. Five of the six animals showed well-defined erythema on the abraded skin at 24 hours after dosing. Very slight erythema in all animals and oedema in 2/6 animals were reported, which persisted after 72 hours post dosing on abraded skin (REACHa).

In another skin irritation study conducted in six New Zealand White rabbits, 0.5 mL of sodium AOS solution (38 % active) was applied dermally to shaved, intact and abraded skin for four hours under semi-occlusion. The applied site was washed to remove the test substance. All six animals showed moderate to severe reactions with eschar formation, one with cracking at the treatment site at 72 hours after dosing. The reactions were slightly worse in abraded skin than intact skin (REACHa).

In an irritation study conducted according to OECD TG 404, 0.5 g of sodium AS powder (88.7 % purity) was applied dermally (semi-occlusive) to three New Zealand White rabbits for four hours. Erythema and moderate oedema were observed up to seven days after the patches were removed. All signs of irritation were completely resolved 14 days after dosing (REACH).

Skin irritation (erythema and oedema) was also reported following a four-hour application of 5–25% SLS solution on intact rabbit skin (NICNASa). SLS is classified as hazardous with the risk phrase 'Irritating to skin' in the HSIS (Safe Work Australia).

Eye Irritation

The chemicals in this group are considered severe eye irritants warranting hazard classification. Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

In an eye irritation study conducted according to OECD TG 405, 0.1 mL of sodium AOS (30 % active) was applied to the eyes of three New Zealand White rabbits and observed for 21 days. Observed effects included slight corneal redness, slight iritis and conjunctival effects (erythema, swelling and chemosis). Except for chemosis, all eye irritation effects persisted for up to 21 days (REACHa).

In another eye irritation study conducted in six New Zealand White rabbits, 0.1 mL of sodium AOS (38% active) was applied to the eyes with or without washing. Observation times were 24, 48 and 72 hours after administration. Eye irritation effects, which persisted for up to 72 hours, were reported (REACHa; HERA 2002).

The eyes of three New Zealand White rabbits were treated with concentrated (0.08 mL of 90 % solution) sodium AOS. The test material was washed off and effects were observed at 24, 48 and 72 hours after application. Observed effects included clear to diffused beefy red erythema and severe swelling of the conjunctivae. Circumcorneal injection (enlargement of the ciliary and conjunctival blood vessels), corneal opacity and discharge (colourless, which changed to white viscous discharge) were also reported. The effects persisted for up to 21 days after dosing (REACHa).

Sodium AS administered at 6 % resulted in eye irritation in rabbits, which was reversible within 72 hours of dosing (REACH).

The chemical, SLS at 25% in an aqueous solution caused eye irritation in rabbit eyes, which were not reversible within the 21-day observation period (NICNASa). SLS is classified as hazardous with the risk phrase 'Risk of serious damage to eye' in the HSIS (Safe Work Australia).

Observation in humans

Based on the available information, the chemicals in this group have been reported to have irritation potential in humans. Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

In a dermal irritation study, human cadaver skin was soaked in sodium olefin sulfonates (C10, 12, 14, 16 and 18) for one, three, six and 24 hour and was compared with skin soaked in distilled water for the same period. Maximum swelling was seen for the C12 and C14 olefin sulfonates (REACHa).

In a controlled human exposure, repeated application of 1 % alkyl sulfates to the skin of human volunteers did not produce adverse reactions, while concentrations of 10 % were regarded as moderate to strong irritants (HERA, 2002).

Clinical studies in humans reported that SLS caused skin irritation following patch testing at a ≥2 % concentration. The irritation increases with increasing concentration and length of contact with the skin (NICNASa).

The chemical, SLS has been reported to cause irritation in the respiratory tract and oral mucosa, especially in individuals predisposed to recurrent mouth ulcers (NICNASa).

It has also been reported that SLS was the most common cause of eye irritation in commercial shampoos (NICNASa).

Sensitisation

Skin Sensitisation

Based on the available information, the chemicals in this group are not skin sensitisers. Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium olefin sulfonate and sodium alkyl sulfate.

Sodium AOS and sodium AS did not induce sensitisation reactions in several guinea pig maximisation tests or in a Buehler test (HERA, 2002; OECD, 2007; REACHa; REACH).

The chemical, SLS produced positive reactions in 2/3 local lymph node assays (LLNA). However, the observed increase in cell proliferation was caused by a non-antigen-specific proliferative stimulus induced by the irritating effect of the tested SLS concentrations (4, 5, 10 or 25 %). SLS was not considered as a skin sensitiser (NICNASa).

Observation in humans

The chemicals in this group are not considered to be skin sensitisers in humans (OECD, 2007; NICNASa; NICNASb).

In a repeated patch test on humans, sodium AOS at a concentration of 8% was not considered a sensitiser in 88 volunteers. The chemical was reported to have caused considerable irritation but no sensitisation. The chemicals in this group are used extensively in consumer products. The low incidence of sensitisation cases reported indicates that the sensitising potential of the chemicals in this group is also low (OECD, 2007; NICNASa; REACHa).

Repeated Dose Toxicity

Oral

Based on the available data, the chemicals in this group are not considered to cause serious damage to health following repeated oral exposure.

In a 90-day feeding study, rats (strain and number not specified) were fed sodium AOS at doses of 40, 200 or 1000 mg/kg/day. A slight increase in the relative liver weight ratio was observed in animals at the highest dose group. No other treatment-related changes were observed (Arthur D Little, Inc., 1993).

In a 91-day feeding study, groups of rats (strain and number not specified) received sodium AOS (34 % active) at doses of 50, 150 or 500 mg/kg. No treatment-related effects or histopathological changes were observed. No further details were provided (Arthur D Little, Inc., 1993).

In a 104 week study, Sprague Dawley (SD) rats (50 animals/sex/group) were fed sodium AOS at doses of 0, 39, 96 or 195 mg/kg bw/day for males and 0, 57, 132 or 259 mg/kg bw/day for females. No treatment-related systemic effects were observed in the low or mid-dose test groups. In the highest dose group, slight decreases in body weight gain and food intake during the first year of treatment were reported. A no observable adverse effect level (NOAEL) of 96–132 mg/kg bw/day and a lowest observed adverse effect level (LOAEL) of 195–259 mg/kg bw/day were established in this study (OECD, 2007).

Repeated oral administration of alkyl sulfates with chain lengths between C12 and C18 resulted in local irritation at the site of first contact (irritation of the fore stomach). The target organs for systemic toxicity are the liver (increased liver weight, enlargement of liver cells, and increased liver enzyme levels) and the kidneys (increased relative kidney weights). In a 13-week dietary study in rats, an LOAEL of 123 mg/kg bw/day based on liver toxicity, and an NOAEL of 61 mg/kg bw/day were determined for C16–18 sodium AS. An NOAEL of 116 mg/kg bw/day and an LOAEL of 230 mg/kg bw/day were determined in rats administered with C12 sodium AS in a 13-week study (HERA, 2002; OECD, 2007).

Dermal

Based on the available data, the chemicals in this group are considered not to cause serious damage to health following repeated dermal exposure. Dermal administration resulted in local effects consisting of skin irritation at the site of dermal contact.

In a repeated dose dermal toxicity study, sodium AOS was applied to rabbit skin at 0.5 or 1 % daily for 14 days. No skin irritation was reported (Arthur D Little, Inc., 1993; REACHa).

In another study, sodium AOS was applied to rabbit skin at 1 % daily for 28 days. No skin irritation effects were observed on intact skin (REACHa).

In a 91-day study, a 2 mL/kg/day aqueous solution of sodium AOS (34 % active), when applied to the backs of rabbits, showed mild to moderate skin irritation (Arthur D Little, Inc., 1993; REACHa).

In a cumulative open patch test, sodium AOS at 2 % in an aqueous solution was applied to guinea pig skin twice daily for nine applications. Slight to moderate skin irritation was reported (Arthur D Little, Inc., 1993; REACHa).

Repeated dermal administration in mice of sodium C12-15 AS for 21 days (up to 18 % in water) or 13 weeks (up to 15 % in water) resulted in increased relative liver and kidney weights. An NOAEL of 10 % (approximately 400 mg/kg bw/day) for systemic toxicity was determined. For dermal toxicity, an NOAEL of 5 % (approximately 200 mg/kg bw/day) and an LOAEL of 10 % (approximately 400 mg/kg bw/day) were determined based on thickening of the skin, ulceration and necrosis of the epidermis at doses greater than 10 % (HERA, 2002; OECD, 2007).

Inhalation

No data are available.

Genotoxicity

Based on the available information, the chemicals in this group are not genotoxic in either in vitro or in vivo studies. Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

In vitro studies

In several Ames tests, concentrations up to 10000 µg/plate of sodium AOS were negative for point mutations in *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538 with or without metabolic activation (OECD, 2007).

In two separate bacterial reverse mutation assays conducted according to the OECD TG 471, concentrations of up to 10000 sodium AOS and sodium AS were not mutagenic in *S. typhimurium* or *Escherichia coli* with or without metabolic activation (OECD, 2007; REACHa; REACH).

In a chromosomal aberration assay using Chinese hamster lung V79 cells conducted according to the OECD TG 473, 0–200 µg/plate sodium AOS did not induce chromosomal aberration (OECD, 2007; REACHa).

Similar results were reported for AS in several bacterial mutation assays (HERA, 2002; OECD, 2007).

In a mammalian cell gene mutation assay similar to OECD TG 476, sodium AS was not mutagenic both in the presence or absence of metabolic activation (REACH).

The chemical, SLS was not mutagenic in a bacterial reverse mutation assay with or without metabolic activation. It was also not mutagenic in a mouse lymphoma cell forward mutation assay using mouse lymphoma cell L5178Y tk+/tk-, with or without metabolic activation (NICNASa).

In vivo studies

In a gene mutation study, 5000 mg/kg of four samples (21%-38 % active) of sodium AOS was administered intramuscularly in mice. The test substance was not mutagenic in bacteria or yeast when metabolised by mice (Arthur D Little, Inc., 1993; REACHa).

Sodium AS did not induce chromosomal abnormality in mammalian bone marrow chromosome aberration tests or mammalian erythrocyte micronucleus test (OECD, 2007; REACH).

In a chromosome aberration assay, SLS did not induce increases in rearrangements, chromatid gaps and breaks, or isochromatid gaps and breaks in rats fed with 0, 500 or 1000 mg/kg bw/day for 90 days (NICNASa).

In a dominant lethal study conducted in mice, SLS had no effects on pregnancy frequency, number of implantations or frequency of early deaths (NICNASa).

Carcinogenicity

The available information indicate that the chemicals in this group are not carcinogenic. Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

In a carcinogenicity study, Wistar rats (40/sex) were fed diets containing 0, 1, 0.75 or 0.5 % (500, 375 or 250 mg/kg bw/day) of sodium AOS for 24-27 weeks. No increase in tumours was reported at necropsy at the end of the treatment (REACHa).

In another study, CFY (remote Sprague Dawley) rats (50/sex) were fed with a mixture of alkenyl sulfonate and hydroxyalkane sulfonate. The mixture was administered at dietary concentrations of 39, 96 or 195 mg/kg bw/day in males and 57, 132 or 259 mg/kg bw/day in females for 104 weeks. There were no differences reported in the overall incidences of neoplasms compared with controls (Hunter and Benson, 1976; REACHa).

In a dermal exposure study, groups of Swiss Webster mice (40/sex) were treated three times a week with 20 % or 25 % of sodium AOS for 92 weeks. No significant treatment-related toxicity or lesions were reported during the study (Oba and Takei, 1992; REACHa).

In another dermal study, Long Evans rats were treated with sodium AOS for two years. The test substance was applied at a dose of 1 ml/kg (as a 10 % active (v/v) aqueous solution) to the clipped dorsal surface of rats, twice weekly. There were no treatment-related effects reported (REACHa).

The chemical, SLS was not carcinogenic in beagle dogs, although it was reported that the study had various limitations (NICNASa).

Reproductive and Developmental Toxicity

The chemicals did not show specific reproductive or developmental toxicity. Any reproductive or developmental effects were only observed secondary to maternal toxicity (OECD 2007; NICNASa; REACHa; REACH). Data on SLS are provided as read across since SLS has similar physico-chemical properties and reactivity to sodium AOS and sodium AS.

Two generational studies were conducted in pregnant rats (20/dose), mice (20/dose) and rabbits (13/dose). The rodents were treated with sodium AOS by gavage on gestation days (GD) 6–15; while rabbits were treated on GD 6–18. The treatment doses were 0.2, 2, 300 or 600 mg/kg bw/day. No signs of maternal toxicity were observed in any of the treated rats. All rabbits dosed with 600 mg/kg bw/day and one dam dosed with 300 mg/kg bw/day died during the study (HERA, 2002; Palmer et al., 1975; REACHa).

In a number of developmental and reproductive studies, oral administration of sodium AOS did not cause embryotoxic, foetotoxic or teratogenic effects in rats. However, reproductive and developmental effects were observed in mice and rabbits secondary to maternal toxicity. No further details were provided (OECD, 2007; REACHa).

In a reproductive study, Swiss albino male mice were fed with SLS 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). The study concluded that SLS has no adverse effects on fertility when administered at concentrations sufficient to cause a significant reduction in body weight (parental toxicity). An NOAEL of 1000 mg/kg bw/day (in males) for fertility was reported for the study (NICNASa).

In a developmental study using female rats, SLS was administered by oral gavage at 0, 63, 125, 250 or 500 mg/kg bw/day, on GD 6–15. Maternal toxicity was observed at the highest dose; however, no signs of developmental toxicity were reported. The NOAELs for maternal and developmental toxicity were reported to be 250 and >500 mg/kg bw/day, respectively (NICNASa).

In another developmental study using female CD rats, SLS was administered by oral gavage at 0, 0.2, 300 or 600 mg/kg bw/day on GD 6–15. SLS did not cause developmental toxicity at doses up to 600 mg/kg bw/day. Maternal toxicity was observed at 300 mg/kg bw/day. The NOAEL for developmental toxicity was reported to be 600 mg/kg bw/day. In a similar study, mice (CD-1) and rabbits (New Zealand White) were administered by oral gavage with the same doses as above. Maternal toxicity was observed at 300 mg/kg bw/day in both species. The NOAEL for developmental toxicity was reported to be 300 mg/kg bw/day based on total resorption and/or increased incidence of litter loss at the 600 mg/kg bw/day dose in both species (NICNASa).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are local effects including skin irritation and the possibility of causing serious damage to eyes.

Public Risk Characterisation

The chemicals in this group have reported cosmetic and domestic uses in Australia and overseas. Australian and overseas information suggests that the chemicals are generally used at low concentrations in cosmetics and at up to 16.5 % for domestic purposes (i.e. hand dishwashing liquid) (HERA 2002).

Considering the critical health effects identified for these chemicals, the highest concern relates to skin and eye irritation. There is the potential for skin contact to occur when using domestic products such as laundry detergents or hand washing liquid. However, such products are intended to be rinsed off from the skin after use. While there is also the potential for ocular exposure in a domestic setting, this is not likely to be a concern at the concentrations identified in domestic products in Australia and overseas. Based on the available skin and eye irritation studies, the chemicals in this group are not considered to pose a greater risk to public health compared with the other commonly available anionic surfactants. Under typical use conditions, skin or eye contact with these chemicals is not expected to cause significant irritation.

Occupational Risk Characterisation

During product formulation, dermal and ocular exposure may 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, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular exposure 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 the appropriate controls.

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 the chemical in cosmetics and domestic products be managed through changes to poison 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

Appropriate scheduling and labelling should be undertaken to mitigate risk when the chemicals are used in domestic and cosmetic products. Due to the skin and severe eye irritation potential at the concentrations reported to be potentially in use, these chemicals should be considered for listing in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP), consistent with the *Scheduling Policy Framework* guidelines. Exemptions to scheduling might be applicable at low concentrations.

Matters to be taken into consideration include:

- the known and widespread uses of the chemicals as anionic surfactants in cosmetic and domestic products in Australia. These chemicals are reported to be used in cosmetic and domestic (at concentrations up to 16.5 %) products overseas;
- the chemicals at a 10% concentration have been reported to cause moderate to strong skin irritation to humans;
- the chemicals at concentrations =30 % caused severe eye irritation in experimental animals; and
- the chemicals present similar issues as other surfactants already scheduled in the SUSMP, including SLS.

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 and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41) Irritating to skin (Xi; R38)	Causes serious eye damage - Cat. 1 (H318) 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 chemicals should be used according to the instructions on the label.

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 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 which could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- 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.

References

Arthur D Little, Inc 1993. Environmental and human safety of major surfactants, Volume 1. Anionic surfactants. Part 4. Alpha Olefin Sulfonates. National Technical Services (NTIS) report No PB94-102423.

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

Hazardous Substances Data Bank (HSDB). National Library of Medicine. Accessed March 2015 at **http://toxnet.nlm.nih.gov**.

Human& Environmental Risk Assessment (HERA, 2002) on Alcohol sulfates at **http://www.heraproject.com/files/3-hh-04-%20hera%20as%20hh%20web%20wd.pdf**

Hunter, B and Benson, HG 1976. Long-term toxicity of the surfactant alpha-olefin sulphonate (AOS) in the rat. Toxicology 5; 359-370.

Inoue S, O'Grodnick JS, and Tomizawa S 1982. Metabolism of alpha-olefin sulfonate (AOS) in rats. Fundamental and Applied Toxicology 2:130-138.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2014) (NICNAS b). Inventory Multi-Tiered and Prioritisation (IMAP): Human Health Tier I Assessment for secondary alkane sulfonates (SAS) (Cas Nos. 68037-49-0,75534-59-7, 93763-92-9, 106233-08-3). Available at **http://www.nicnas.gov.au**

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (NICNAS a). Inventory Multi-tiered Assessment and Prioritisation (IMAP) Human Health Tier II Assessment for sodium, ammonium and potassium lauryl sulfate (CAS Nos 151-21-3, 2235-54-3, 4706-78-9). Available at **http://www.nicnas.gov.au**

Oba, K and Takei, R 1992. Carcinogenic, mutagenic/genetic toxicity and teratogenic properties. In Anionic surfactants; biochemistry, toxicology and dermatology. 2nd ed. Surfactant science series. Vol. 43. Eds. C Gloxhuber and K Kunstler, 331-409. New York: Marcel Dekker.

OECD 2007. SIAR on category of Alkyl sulfates, Alkane sulfonates and a-Olefin sulfonates. Accessed March 2015 at **http://webnet.oecd.org/hpv/UI/SIDS_Details.aspx?Key=d796277d-731b-4839-a21d-e22296ecc80a&idx=0OECD**, 2007

Palmer AK, Readshaw MA and Neuff AM, 1975. Assessment of the teratogenic potential of surfactants. Part II- AOS. Toxicology 3; 107-113.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Dossier. Sulfuric acid, mono-C12-18-alkyl esters, sodium salts (CAS No. 68955-19-1). Accessed March 2015 at **http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances**

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACHa) Dossier. Sulfuric acid, C14-16(even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts (CAS No. 68439-57-6). Accessed May 2015 at **http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c860e43-3add-069e-e044-00144f67d249/AGGR-0d7bdc9d-450d-46fd-9e00-7d95b1f8ece9_DISS-9c860e43-3add-069e-e044-00144f67d249.html#section_1.1**

The Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) 2015. Accessed June 2015 at **http://www.comlaw.gov.au/Details/F2015L00128**

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Chemical Identities

Chemical Name in the Inventory and Synonyms	**Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts** sodium C14-16-olefin sulfonate sodium C14-16-alkane hydroxy and C14-16-olefin sulfonates alkenes, C14-16 alpha-, sulfonated, sodium salts sodium tetradecenesulfonate sodium a-olefin sulfonate sodium (C14-16) olefin sulfonate
CAS Number	68439-57-6
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	298.42-344.49

Chemical Name in the Inventory and Synonyms	**Sulfuric acid, mono-C12-18-alkyl esters, sodium salts** sulfuric acid, C12-18-alkyl (even numbered) esters, sodium salts sulfuric acid monoalkyl(C12-18) esters, sodium salts sodium alkyl sulfate tallow alkyl sulfate (TAS)
CAS Number	68955-19-1
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	288.38-372.54

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