Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Medium and long chain alkyl sulfates

Evaluation statement

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Draft

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AICIS evaluation statement

Subject of the evaluation

Medium and long chain alkyl sulfates

Chemicals in this evaluation

Name	CAS registry number
Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	139-96-8
Sulfuric acid, monooctyl ester, sodium salt	142-31-4
Sulfuric acid, monodecyl ester, sodium salt	142-87-0
Sulfuric acid, monododecyl ester, compound with 2,2'-iminobis[ethanol] (1:1)	143-00-0
1-Hexadecanol, hydrogen sulfate	143-02-2
Sulfuric acid, monooctadecyl ester	143-03-3
Sulfuric acid, monododecyl ester	151-41-7
1-Hexadecanol, hydrogen sulfate, sodium salt	1120-01-0
Sulfuric acid, monooctadecyl ester, sodium salt	1120-04-3
1-Tetradecanol, hydrogen sulfate, sodium salt	1191-50-0
Sulfuric acid, monohexyl ester, sodium salt	2207-98-9
1-Tridecanol, hydrogen sulfate, sodium salt	3026-63-9
1-Tetradecanol, hydrogen sulfate, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	4492-78-8
Sulfuric acid, monooctadecyl ester, ammonium salt	4696-46-2
1-Hexadecanol, hydrogen sulfate, ammonium salt	4696-47-3
Sulfuric acid, monododecyl ester, compound with 2-aminoethanol (1:1)	4722-98-9
1-Eicosanol, hydrogen sulfate, sodium salt	13177-49-6
Sulfuric acid, monodecyl ester, ammonium salt	13177-52-1
Sulfuric acid, monododecyl ester, compound with 1-amino-2-propanol (1:1)	21142-28-9
1-Tetradecanol, hydrogen sulfate, magnesium salt	25446-91-7
Sulfuric acid, monoisononyl ester, sodium salt	26856-96-2

Name	CAS registry number
Sulfuric acid, monooctyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	30862-34-1
Sulfuric acid, monodecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	39943-70-9
1-Hexadecanol, 1-(hydrogen sulfate), compd. with 2,2'-iminobis[ethanol] (1:1)	51541-51-6
Sulfuric acid, monododecyl ester, compound with 2-(diethylamino) ethanol (1:1)	65104-49-6
Sulfuric acid, monododecyl ester, compound with 1,1',1''-nitrilotris[2-propanol]	66161-60-2
Sulfuric acid, mono-C10-16-alkyl esters, ammonium salts	68081-96-9
Sulfuric acid, mono-C10-16-alkyl esters, magnesium salts	68081-97-0
Sulfuric acid, mono-C8-18-alkyl esters, sodium salts	68130-43-8
Sulfuric acid, mono-C6-10-alkyl esters, ammonium salts	68187-17-7
Isodecanol, hydrogen sulfate, sodium salt	68299-17-2
Sulfuric acid, mono-C10-16-alkyl esters, compounds with diethanolamine	68585-44-4
Sulfuric acid, mono-C10-16-alkyl esters, sodium salts	68585-47-7
Sulfuric acid, mono-C12-15-alkyl esters, compounds with triethanolamine	68815-25-8
Sulfuric acid, mono-C12-15-alkyl esters, sodium salts	68890-70-0
Sulfuric acid, mono-C10-16-alkyl esters, compounds with ethanolamine	68908-44-1
Sulfuric acid, mono-C10-16-alkyl esters, compounds with isopropanolamine	68910-01-0
Sulfuric acid, mono-C12-18-alkyl esters, sodium salts	68955-19-1
Sulfuric acid, mono-C16-18-alkyl esters, sodium salts	68955-20-4
Sulfuric acid, mono-C9-13-alkyl esters, sodium salts	72906-11-7
Sulfuric acid, mono-C12-16-alkyl esters, sodium salts	73296-89-6
Sulfuric acid, mono-C9-11-alkyl esters, sodium salts	84501-49-5
Sulfuric acid, mono-C12-16-alkyl esters, compounds with triethanolamine	85252-21-7
Sulfuric acid, mono-C12-14-alkyl esters, sodium salts	85586-07-8
Sulfuric acid, mono-C8-18-alkyl esters, magnesium salts, compounds with triethanolamine	85586-38-5
Sulfuric acid, mono-C8-14-alkyl esters, compounds with triethanolamine	85665-45-8
Sulfuric acid, mono-C12-14-alkyl esters, compounds with isopropanolamine	85681-66-9

Name	CAS registry number
Sulfuric acid, mono-C8-14-alkyl esters, ammonium salts	90583-10-1
Sulfuric acid, mono-C12-18-alkyl esters, ammonium salts	90583-13-4
Sulfuric acid, mono-C12-14-alkyl esters, compounds with ethanolamine	90583-16-7
Sulfuric acid, mono-C12-14-alkyl esters, compounds with triethanolamine	90583-18-9
Sulfuric acid, mono-C8-18-alkyl esters, magnesium salts	90583-22-5
Sulfuric acid, mono-C12-14-alkyl esters, magnesium salts	90583-23-6
Sulfuric acid, mono-C6-12-alkyl esters, sodium salts	90583-25-8
Sulfuric acid, monococo alkyl esters, sodium salt	97375-27-4

Reason for the evaluation

Evaluation Selection Analysis indicated a potential human health and environmental risk.

Parameters of evaluation

These chemicals are a group of structurally similar, medium to long chain (C6—C20) alkyl sulfates and alkyl sulfuric acids that are listed on the Australian Inventory of Industrial Chemicals (the Inventory). This group of chemicals belongs to a widely used class of anionic surfactants. This evaluation is a human health and environmental risk assessment of identified industrial uses of the chemicals in Australia.

These chemicals have been assessed as a group as they have similar use patterns and are expected to produce alkyl sulfate anions at the pH of biological solutions, or in the environment. The cation components are not expected to contribute significantly to the toxicity of these chemicals.

The risks posed to the environment associated with the industrial uses of these chemicals have been evaluated according to the following parameters:

- introduction to Australia at up to 9,999 tonnes/year
- expected release into sewage treatment plants (STPs) due to consumer and commercial use.

In this evaluation, chemical names have been abbreviated to include chain length or range, and counter ion, where relevant. For example:

- the sodium salt of decyl sulfate is abbreviated to C10 AS Na
- the UVCBs (unknown or variable composition, complex reaction products or of biological origin) sulfuric acid, mono-C10-16-alkyl esters, sodium salts is abbreviated to C10-16 AS Na.

Use of these chemicals in oil or gas extraction and processing have not been assessed in this evaluation.

Summary of evaluation

Summary of introduction, use and end use

Alkyl sulfates are surfactants used in a variety of consumer and commercial products worldwide. Available Australian and international data indicate that these chemicals are used in high volumes (>1,000 tonnes).

Although limited specific Australian use information is available, the chemicals in this evaluation are expected to have similar uses in Australia compared with the identified international uses.

These chemicals have widespread use in both personal care products and household cleaning products. Maximum reported concentrations for some of these chemicals are:

- leave-on cosmetic products – 8%

- rinse-off cosmetic products – 40%
- diluted for bath use – 15%
- cleaning products (including spray applications) – 5%
- dishwashing liquid – 18%
- laundry detergent (powder and liquid) – 30%.

The chemicals have many commercial uses including in fire-fighting foams and site-limited uses in chemical and polymer manufacture.

Human health

Summary of health hazards

The identified health hazards are based on available data for these chemicals, or structurally similar chemicals.

Based on the available data these chemicals:

- have low acute dermal toxicity
- are not considered to be skin sensitisers
- are not expected to cause serious systemic health effects following repeated exposure
- are not expected to cause specific adverse effects on fertility/sexual function and foetal development
- are not expected to have genotoxic potential
- are not expected to be carcinogenic.

Based on available data, these chemicals are considered to have low to moderate acute oral toxicity. While available data indicates C8 AS Na has low acute oral toxicity, in general, the median lethal dose (LD50) values decrease with increasing chain lengths, with LD50 values <2,000 mg/kg bw generally reported for alkyl sulfates with a chain length C12 and below . For the UVCBs, effects will depend on the composition.

No hazard data are available for the alkyl sulfuric acids in this group. Based on the strong acidic nature, these chemicals are expected to be corrosive to skin and cause serious eye damage.

The alkyl sulfates are irritating to skin with varying degrees of severity. There are limitations in the available studies, including variability in test substance purity and composition, and inconsistencies in the reporting of effects. However, the available data indicate that the severity of effects generally decrease with increasing chain length. In animal studies there is evidence of destruction of skin tissue following 4-hour exposure to alkyl sulfates containing C8 and C10 chain lengths. The corrosive nature of these chemicals is also supported by in vitro studies. Based on the available data, in the absence of specific information, corrosivity is also expected for C6 and C9 alkyl sulfates. The weight of evidence also supports that alkyl sulfates with carbon chains of C12 to C15 are moderate to severe irritants but with limited reported incidence of necrosis. Alkyl sulfate salts with carbon chains of C16 to C18 are slightly irritating to skin at tested concentrations. Slight irritation is also expected for C20 members. For the UVCBs, skin irritation effects will depend on the composition. Consistent with the surfactant properties, alkyl sulfates produce dermal effects in a dose dependent manner, with increasing concentration resulting in increased severity of effects. Based on human data (see **Corrosion/Irritation – Observation in humans**) minimal irritation is expected at concentrations <1%.

The majority of these chemicals are expected to cause serious eye damage. Irreversible eye damage was reported in several eye irritation studies conducted according to OECD TG 405. The eye irritating potential appears to decrease with increasing alkyl chain length. The available data indicates that alkyl sulfates with carbon chains of C16 to C18 cause less severe effects, although reversible eye irritation effects (conjunctival redness score 2.3) were still observed.

Based on the limited available data, chemicals in this group are not likely to cause serious systemic effects following repeated oral or dermal exposure. However, due to their skin irritating effect, they may compromise the integrity of the skin and increase dermal absorption of other chemicals present in product formulations. Necrosis and ulceration of the skin were noted in test animals following long term repeated exposures.

Limited inhalation data are available. Given the irritant properties of these chemicals, inhalation could lead to irritation/corrosion of the mucous membranes of the respiratory tract.

For further details of the health hazard information see **Supporting information**.

Hazard classifications relevant for worker health and safety

These chemicals satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety as follows. This does not consider classification of physical hazards.

The chemicals in this evaluation which are UVCBs have been classified according to the criteria for mixtures, based on the “summation method” and the expected alkyl chain length distribution (UNECE 2017).

The proposed hazard classification is based on read across principles and available composition data. It should be used as a default for these chemicals. If empirical data become available for a specific chemical, this data may be used to amend the default classification for that chemical.

The 3 alkyl sulfuric acids in this group (C16 AS; CAS No. 143-02-2), sulfuric acid, monooctadecyl ester (C18 AS; CAS No. 143-03-3) and sulfuric acid, monododecyl ester (C12 AS; CAS No. 151-41-7) are classified according to the table below:

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritation	Skin Corr. 1	H314: Causes severe skin burns and eye damage
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage

The following chemicals are classified according to the table below:

- C6 alkyl sulfates (CAS No. 2207-98-9)
- C8 alkyl sulfates (CAS No. 142-31-4 (except acute oral toxicity); 30862-34-1)
- C9 alkyl sulfates (CAS No. 26856-96-2)
- C10 alkyl sulfates (CAS No. 142-87-0; 13177-52-1; 68299-17-2; 39943-70-9)
- C6–10 alkyl sulfates (CAS No. 68187-17-7)
- C6–12 alkyl sulfates (CAS No. 90583-25-8)

- C9–11 alkyl sulfates (CAS No. 84501-49-5)
- C9–13 alkyl sulfates (CAS No. 72906-11-7)
- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- Coco alkyl sulfates (CAS No. 97375-27-4).

Health hazards	Hazard category	Hazard statement
Acute toxicity	Acute Tox. 4	H302: Harmful if swallowed
Skin corrosion/irritation	Skin Corr. 1C	H314: Causes severe skin burns and eye damage
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage

The following chemicals are classified according to the table below:

- C12 alkyl sulfates (139-96-8; 143-00-0; 4722-98-9; 21142-28-9; 65104-49-6; 66161-60-2)
- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0).

Health hazards	Hazard category	Hazard statement
Acute toxicity	Acute Tox. 4	H302: Harmful if swallowed
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage

The following chemicals are classified according to the table below:

- C13 alkyl sulfates (CAS No. 3026-63-9)
- C14 alkyl sulfates (CAS No. 1191-50-0; 4492-78-8; 25446-91-7)
- C12–14 alkyl sulfates (CAS No. 85586-07-8; 85681-66-9; 90583-16-7; 90583-18-9; 90583-23-6)
- C12–15 alkyl sulfates (CAS No. 68815-25-8; 68890-70-0)
- C12–16 alkyl sulfates (CAS No. 73296-89-6; 85252-21-7)
- C12–18 alkyl sulfates (CAS No. 68955-19-1, 90583-13-4).

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage

The following chemicals are classified according to the table below:

- C16 alkyl sulfates (CAS No. 1120-01-0; 4696-47-3; 51541-51-6)
- C18 alkyl sulfates (CAS No. 1120-04-3; 4696-46-2)
- C20 alkyl sulfates (CAS No. 13177-49-6)

- C16–18 alkyl sulfates (CAS No. 68955-20-4).

Health hazards	Hazard category	Hazard statement
Serious eye damage/eye irritation	Eye Irrit. 2	H319: Causes serious eye irritation

Summary of health risk

Public

Based on the available use information, the public may be exposed to these chemicals by:

- direct application of products containing the chemicals to the skin and hair
- inhalation if products if aerosolised
- incidental skin and eye contact with these chemicals during use of domestic products
- exposure of children to these chemicals by accidentally ingesting liquid laundry detergent products.

The main route of exposure to these chemicals is expected to be via the skin. Incidental inhalation, ingestion and contact with the eyes may also occur.

The critical health effect for risk characterisation of these chemicals is skin and eye irritation. Based on use information for alkyl sulfates, these chemicals are expected to be present in cosmetics at concentrations up to 40%, and in domestic cleaning and laundry products at concentrations up to 30%.

The hazard profile and risks are similar to a large number of surfactants that are extensively used in products, with severity dependent on concentration and pH. The risks are reduced when products are formulated to be non-irritating. Additionally, chemicals in this group are frequently formulated with related chemicals with similar toxicity including alcohol ethoxylates and alkyl benzene sulfonates. Therefore, the risk may be impacted by the cumulative levels of surfactants.

The C12 alkyl sulfates in this group are currently covered by the entries Schedule 6 of the *Poisons Standard* (SUSMP) (See **Existing Australian regulatory controls - Public**) (TGA 2024), under which warning statements relating to eye irritation effects apply. Given that other chemicals in this evaluation (other than alkyl sulfates with chain lengths greater than or equal to 16) have similar identified health hazards, there is still a potential risk to the public that requires management (see **Proposed means for managing risks** section). The risk could be managed by through controls under the *Poisons Standard*. Any controls for these chemicals should be considered as part of a broader review of the management of surfactants in the *Poisons Standard* (SUSMP).

Accidental exposure of children to similar chemicals by ingestion and eye and skin contact, has occurred from liquid laundry detergent capsules, leading to adverse effects. In 2013, an Australian Industry Guideline for Labelling & Packaging of Liquid Laundry Capsules was published by the industry. In 2015, the Australian Competition & Consumer Commission (ACCC) participated in a joint international campaign on liquid laundry detergent capsule risks. The focus was to raise awareness of laundry pod safety, including developing a consistent set of safety information for parents and carers worldwide. The ACCC records since 2019 indicate that there has not been any reported complaints or incidents of laundry capsule ingestions.

Workers

During product formulation and packaging, dermal, ocular and inhalation exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to these chemicals at lower concentrations could also occur while using formulated products containing these chemicals. The level and route of exposure will vary depending on the method of application and work practices employed. Good hygiene practices to minimise incidental oral exposure are expected to be in place.

Given the local health effects, these chemicals could pose a risk to workers. Control measures to minimise dermal, ocular and inhalation exposure are needed to manage the risk to workers (see **Proposed means for managing risks** section).

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds (DCCEEW 2022) and based on the available data, the C14 alkyl sulfate chemicals (CAS No. 1191-50-0; 4492-78-8; 25446-91-7) and the C16 alkyl sulfate chemicals (CAS No.143-02-2; 1120-01-0; 4696-47-3; 51541-51-6) are:

- not persistent (Not P)
- not bioaccumulative (Not B)
- toxic (T)

All other chemicals in the evaluation are:

- not persistent (Not P)
- not bioaccumulative (Not B)
- not toxic (Not T)

Environmental hazard classification

These chemicals satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for environmental hazards. This does not consider classification of physical hazards.

The alkyl chain length of the chemicals in this evaluation influences the aquatic toxicity. The chemicals in this evaluation which are UVCBs have been classified according to the criteria for mixtures, based on the “summation method” and the expected alkyl chain length distribution (UNECE 2017).

The proposed hazard classification is based on read across principles and available composition data (see **Supporting information**). It should be used as a default for these chemicals. If empirical data become available for a specific chemical, this data may be used to amend the default classification for that chemical.

The following chemicals are classified according to the table below:

- C10 alkyl sulfates (CAS No. 142-87-0; 13177-52-1; 68299-17-2; 39943-70-9)

- C18 alkyl sulfates (CAS No. 143-03-3; 1120-04-3; 4696-46-2)
- C20 alkyl sulfates (CAS No. 13177-49-6)
- C6–10 alkyl sulfates (CAS No. 68187-17-7)
- C6–12 alkyl sulfates (CAS No. 90583-25-8)
- C9–11 alkyl sulfates (CAS No. 84501-49-5).

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 2	H401: Toxic to aquatic life

The following chemicals are classified according to the table below:

- C12 alkyl sulfates (CAS No. 151-41-7; 139-96-8; 143-00-0; 4722-98-9; 21142-28-9; 65104-49-6; 66161-60-2)
- C13 alkyl sulfates (CAS No. 3026-63-9)
- C9–13 alkyl sulfates (CAS No. 72906-11-7).

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 2	H401: Toxic to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects

The following chemicals are classified according to the table below:

- C14 alkyl sulfates (CAS No. 1191-50-0; 4492-78-8; 25446-91-7)
- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0)
- C12–14 alkyl sulfates (CAS No. 85586-07-8; 85681-66-9; 90583-16-7; 90583-18-9; 90583-23-6)
- C12–15 alkyl sulfates (CAS No. 68815-25-8; 68890-70-0)
- C12–16 alkyl sulfates (CAS No. 73296-89-6; 85252-21-7)
- C12–18 alkyl sulfates (CAS No. 68955-19-1, 90583-13-4)
- Coco alkyl sulfates (CAS No. 97375-27-4).

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 1	H400: Very toxic to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects

The following chemicals are classified according to the table below:

- C16 alkyl sulfates (CAS No. 143-02-2; 1120-01-0; 4696-47-3; 51541-51-6)
- C16–18 alkyl sulfates (CAS No. 68955-20-4).

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 1	H400: Very toxic to aquatic life

Summary of environmental risk

Alkyl sulfates have cumulative domestic use volumes approximately up to 9,999 tonnes per year. These chemicals are used widely as surfactants in consumer and commercial cleaning products and are released to wastewater as a normal part of their use pattern.

Most alkyl sulfates are not toxic according to Australian threshold values. C14 and C16 alkyl sulfates are toxic according to Australian thresholds. All alkyl sulfates have low bioaccumulation potential and are not persistent.

Based on measured international concentrations in sewage treatment plant (STP) effluent and surface waters, alkyl sulfates are expected to be present in Australian surface waters at concentrations below the level of concern.

As the calculated risk quotients (RQs) obtained for alkyl sulfates in various waters are less than 1. Therefore, the current industrial use of these chemicals in Australia is not expected to pose a significant risk to the environment.

Proposed means for managing risk

Public health

It is recommended that the delegate of the Secretary for the Scheduling of Medicines and Chemicals review the schedule entry for lauryl sulfate salts in the *Poisons Standard (the SUSMP)* to more broadly capture alkyl sulfates.

In order to manage the potential risk associated with the use of these chemicals, similar labelling requirements currently in place for lauryl sulfates could be applied to alkyl sulfates with chain lengths less than C16.

Consideration should be given to the following:

- These chemicals have identified use in cosmetic and household cleaning and laundry products.
- Alkyl sulfates with chain lengths less than C16 cause irreversible eye damage in studies in animals.
- The skin irritation potential decreases with increasing chain length, with moderate irritation or corrosion observed for alkyl sulfates chain lengths less than C16
- UVCBs are not captured by the current schedule entry.
- Any controls for these chemicals should also be considered as part of a broader review of the management of surfactants in the *Poisons Standard* (SUSMP) by the TGA.

Workers

Recommendation to Safe Work Australia

It is recommended that Safe Work Australia (SWA) update the Hazardous Chemical Information System (HCIS) to include classifications relevant to work health and safety.

Information relating to safe introduction and use

The information in this statement including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Control measures that could be implemented to manage the risk arising from ocular, dermal and inhalation exposure to these chemicals include, but are not limited to:

- using closed systems or isolating operations
- minimising manual processes and work tasks through automating processes
- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with these chemicals.

Measures required to eliminate or manage risk arising from storing, handling and using these hazardous chemicals depend on the physical form and how these chemicals are used.

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.

Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Conclusions

The Executive Director proposes to be satisfied that the identified risks to human health and the environment from the introduction and use of the industrial chemicals can be managed.

Note:

1. Obligations to report additional information about hazards under *Section 100* of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Grouping rationale

These chemicals have been assessed as a group as they have similar use and environmental release patterns and are expected to have similar critical health and environmental effects.

These chemicals are structurally similar anionic surfactants, with a predominantly linear alkyl chain and a terminal sulfate group. The hydrophobic hydrocarbon chain with a length C6–C20, and the polar sulfate group, confer surfactant properties and enable the use of these substances as anionic surfactants. The structural similarities result in physico-chemical properties and environmental fate characteristic which follow a regular pattern. These chemicals are expected to dissociate to form their corresponding alkyl sulfate anions after release to the environment or at the pH of biological solutions. The cation components are not expected to contribute significantly to the toxicity of these chemicals.

Common physical and/or biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for essentially identical or very similar hazard profiles.

Sulfuric acid, mono-C12-18-alkyl esters, sodium salts (CAS No. 68955-19-1) and some related alkyl sulfates, sodium dodecyl sulfate (AS C12) and other anionic surfactants have previously been evaluated by AICIS (formerly NICNAS) for risks to human health and/or the environment. Relevant hazard and exposure information from these prior assessments has been considered in this evaluation.

Chemical identity

The chemicals in this group consist of a linear, or mostly linear, alkyl chain and a terminal sulfate group.

The alkyl chains are between 6 and 20 carbon atoms long (C6–C20) and are expected to be fully saturated. Many of the chemicals are not defined substances, but are UVCBs (unknown or variable composition, complex reaction products or of biological origin), comprising of different chain lengths.

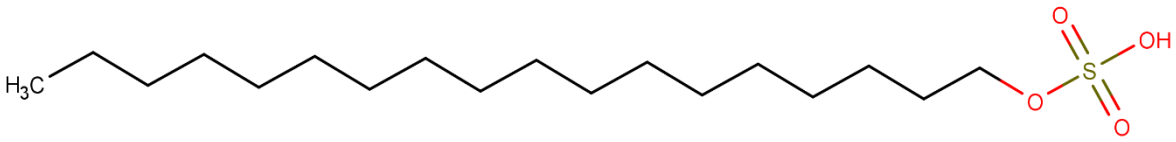
Alkyl sulfates are produced by sulfation of primary alcohols using sulfur trioxide or chlorosulfonic acid (AISE and Cefic 2002; OECD 2007), which yields free sulfuric acids (or hydrogen sulfates). These acids can be neutralised with a base to form the ionised alkyl sulfate chemicals. The counter ion may be a metal (such as sodium or magnesium) or an amine (ammonium ion or primary, secondary, or tertiary amine).

The carbon chain distribution of the chemicals in this evaluation will vary depending on the precursor alcohols. The alcohols derived from vegetable or animal sources, via oleochemical processes, or through Ziegler alcohol synthesis are expected to be linear (AISE and Cefic 2002; OECD 2007). These alcohols contain alkyl chains of even numbered carbons only. Alcohols derived from oxo-processes are expected to be mostly linear with a minor proportion of methyl-branched alcohols. These alcohols may have alkyl chains of even or odd numbered carbons (Thomas et al. 2015).

Information for representatives of these chemicals (an alkyl sulfuric acids, a metal salt and an amine salt in this group) is tabulated below:

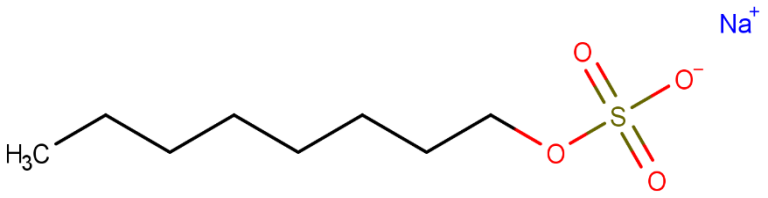
Chemical name	Sulfuric acid, monooctadecyl ester
CAS No.	143-03-3
Synonyms	octadecyl sulfate
Molecular formula	C18H38O4S
Molecular weight (g/mol)	350.56
SMILES (canonical)	O=S(=O)(O)OCCCCCCCCCCCCCCCCCC
Chemical description	-

Structural formula:



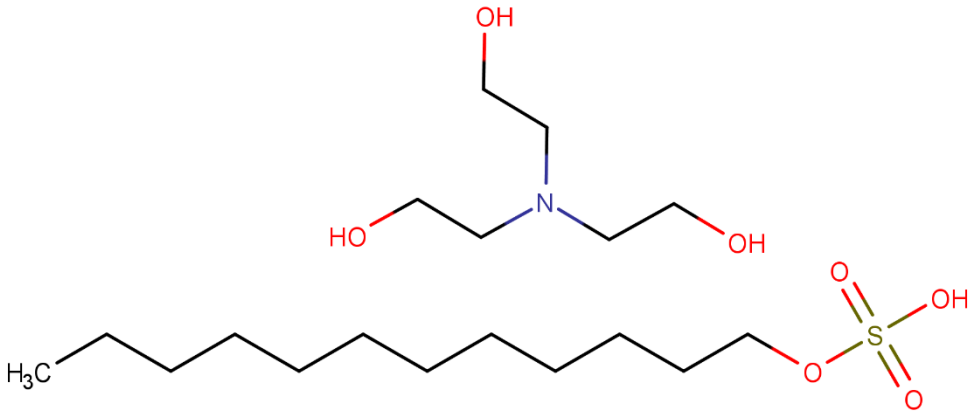
Chemical name	Sulfuric acid, monooctyl ester, sodium salt
CAS No.	142-31-4
Synonyms	sodium octyl sulfate
Molecular formula	C8H18O4S.Na
Molecular weight (g/mol)	232.28
SMILES (canonical)	[Na].O=S(=O)(O)OCCCCCCCC
Chemical description	-

Structural formula:



Chemical name	Sulfuric acid, monododecyl ester, compound with 2,2',2''-nitrilotris[ethanol] (1:1)
CAS No.	139-96-8
Synonyms	triethanolamine lauryl sulfate
Molecular formula	C12H26O4S.C6H15NO3
Molecular weight (g/mol)	415.6
SMILES (canonical)	O=S(=O)(O)OCCCCCCCCCCCC.OCCN(CCO)CCO
Chemical description	-

Structural formula:



Relevant physical and chemical properties

Measured physical and chemical properties for alkyl sulfates were retrieved from the registration dossier for the chemical submitted under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation in the European Union (EU) (REACH n.d.-a; REACH n.d.-b; REACH n.d.-c; REACH n.d.-d), and the scientific literature (Könnecker et al. 2011; OECD 2007):

Chemical name	C8 AS Na	C12 AS Na	C16 AS Na
Physical form	Solid	Solid	Solid
Melting point	181–183°C (exp.)	193–207°C (exp.)	190–192°C (exp.)
Boiling point	ca. 218°C (exp., decomp.)	216°C (exp.)	ca. 232°C (exp., decomp.)
Critical micelle concentration (CMC)	30.2 g/L (exp.)	2.36 g/L (exp.)	0.19 g/L (exp.)
Ionisable in the environment?	Yes	Yes	Yes
pKa	-	1.31	-
log K_{ow}	-	0.83 (exp.)	-0.44

The chemicals in this evaluation are surfactants, therefore the critical micelle concentration (CMC) of selected chemicals has been reported instead of water solubility. The CMCs for alkyl sulfates decrease with increasing alkyl chain length (Cowan-Ellsberry et al. 2014).

The chemicals in this evaluation are strong acids, or salts of strong acids, and are expected to dissociate completely in the pH range of environmental waters and biological fluids. These chemicals are expected to have very low vapour pressures due to their ionic nature (OECD 2007). Additionally, in the environment, these chemicals are not expected to be volatile from water or water surfaces.

Experimental log K_{ow} values are available for some of the chemicals in this evaluation. However, they are not expected to be a good descriptor of hydrophobicity as surfactants tend to concentrate between phase boundaries instead of equilibrating in the phases (OECD 2007).

Different counterions influence the physico-chemical properties of the undissociated chemicals. However, the compounds exist in the dissociated state under environmental conditions and so the influence of the counterion is not considered (Könnecker et al. 2011).

Introduction and use

Australia

The ammonium salt of C10–16 alkyl sulfates (C10–16 AS NH_4: CAS No. 68081-96-9) was reported to have a volume of use of 1,000–9,999 tonnes/year based on information provided to the former National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the 2006 Australian High Volume Industrial Chemicals List (NICNAS 2006). The reported use category was cleaning/washing agents and additives (in cosmetic applications) (NICNAS 2006).

Based on information previously reported under NICNAS, the combined volume of use of the structurally related chemicals sodium lauryl sulfate and ammonium dodecyl sulfate in Australia is in the range 1,000–2,000 tonnes/year. Reported information indicated comparatively lower use of C12-18 AS Na (CAS No. 68955-19-1).

The use of C6-10 AS NH_4 (CAS No. 68187-17-7) in coal seam gas extraction processes has also been reported (NICNAS 2017) and has been previously evaluated. In this evaluation, use of these chemicals in oil and gas extraction or processing has not been assessed.

Based on available data, 1-hexadecanol, hydrogen sulfate (C16 AS; CAS No. 143-02-2) and sulfuric acid, monooctadecyl ester (C18 AS; CAS No. 143-03-3) are not likely to be introduced for industrial use in Australia (AICIS 2021; AICIS 2023).

International

Available information indicates that these chemicals are used as surfactants in a range of commercial and consumer products worldwide.

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)
- European Commission Cosmetic Ingredients and Substances (CosIng)
- United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary
- the Organisation for Economic Cooperation and Development (OECD) High Production Volume chemical program (HPV)
- the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR)
- United States Food and Drug Administration (US FDA)
- Consumer Product Information Database (CPID) (DeLima Associates n.d.)
- Cosmetic Ingredient Reviews (CIR 2010; CIR 2013).

The medium and long chain alkyl sulfates have widespread use in both personal care products and household products.

Nearly half of the chemicals have reported cosmetic uses as foaming, cleansing, emulsifying and surfactant agents including in:

- hand washes and soaps
- hair shampoos
- body washes
- colourants
- shaving products
- skin care products.

The identified concentrations for these chemicals (CIR 2010, CIR 2013, DeLima Associates n.d) were:

- leave-on products – 0.0009–8%
- rinse-off products – 0.0009–40%
- diluted for bath use – 10–15%.

The predominant domestic use of these chemicals is in household cleaning products including dishwashing liquids and laundry detergents. The quantity of surfactant can vary in different formulations. For example, liquid products may contain double the amount of surfactants compared to powders (Madsen et al. 2001). About 59% of alkyl sulfates used in North America in 2008 was for detergent applications. In these applications, the alkyl sulfate carbon chains are usually in the C12–C18 range (Cowan-Ellsberry et al. 2014).

The maximum identified concentration for these chemicals (DeLima Associates n.d) were:

- cleaning products (including spray applications) – 5%
- dishwashing liquid – 18%
- laundry detergent (powder and liquid) – 30%.

The chemicals have reported commercial uses, including:

- in adhesives and binding agents
- in flame retardant and fire extinguishing fluids
- in pigment, dyes and printing inks
- cleaning products and washing agents
- paints, lacquers and varnishes
- surface treatment.
- in leather tanning industry
- as chemical and physical blowing agents
- in bleaching agents
- in dry cleaning solvents
- in condensation removers
- in dust binding agents
- as anti-set-off agents
- as antifreeze agents
- in photochemicals
- as reprographic agents.

Alkyl sulfates surfactants may be present in a type of synthetic fire-fighting foam (aqueous film-forming foam, AFFF) at concentrations of below 20% (Hossain et al. 2022). A study commissioned by ECHA detected several of these chemicals in commercial products (Nicol et al. 2020), some of which are also on the market in Australia (Fire Response n.d.).

These chemicals have reported site limited uses, including:

- as chemical intermediates
- in plastics and synthetic resins
- in polymers, as crosslinking agents.

The estimated annual consumption of alkyl sulfates in 2003 was 118,000 tonnes in North America, 105,000 tonnes in Western Europe and 11,500 tonnes in Japan (OECD 2007). By 2008, an estimated 51,600 tonnes of alkyl sulfates were used in North America as detergents (Cowan-Ellsberry et al. 2014).

Use of alkyl sulfates is reported to be declining worldwide due to a decrease in consumption of powdered laundry detergents and substitution with other classes of surfactants (Cowan-Ellsberry et al. 2014; OECD 2007).

These chemicals may also have non-industrial pharmaceutical and pesticide uses (OECD 2007), which fall outside the scope of this evaluation.

Existing Australian regulatory controls

Workers

Two of these chemicals are listed in the Hazardous Chemical Information System (HCIS) (SWA n.d.) with the following hazard category and statements for human health:

Sulfuric acid, mono-C6-10 alkyl esters (C6-10 AS; CAS No. 68187-17-7)

Health hazards	Hazard category	Hazard statement
Acute toxicity – oral	Acute Tox. 4	H302 (Harmful if swallowed)
Skin corrosion/irritation	Skin Corr. 1C	H314: Causes severe skin burns and eye damage

Sulfuric acid, mono-C12-18-alkyl esters, sodium salts (CAS No. 68955-19-1)

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage

No exposure standards are available for these chemicals in Australia (SWA n.d.).

Public

No specific controls are currently available for the majority of these chemicals.

Sodium tetradecyl sulfate (CAS No. 1191-50-0) and the lauryl sulfate salts (CAS No.139-96-8; 143-00-0; 4722-98-9; 21142-28-9; 65104-49-6; 66161-60-2) are listed in the *Poisons Standard* (SUSMP) as follows (TGA 2024):

Schedule 4:

“SODIUM TETRADECYLSULFATE in preparations for injection.”

Schedule 6:

“LAURYL SULFATE SALTS (excluding their derivatives) **except**:

a) in wash-off preparations containing 30 per cent or less of lauryl sulfates and, if containing more than 5 per cent of lauryl sulfates, 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 lauryl sulfates;

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

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

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

(i) IF IN EYES WASH OUT IMMEDIATELY WITH WATER; and
(ii) IF SKIN OR HAIR CONTACT OCCURS, REMOVE CONTAMINATED CLOTHING AND FLUSH SKIN AND HAIR WITH RUNNING WATER.”

Schedule 4 chemicals are labelled with ‘Prescription Only Medicine or Prescription Animal Remedy’ and are described as: “Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.”

Schedule 6 chemicals are labelled with 'Poison' and are described as: Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

Following concerns relating to child exposure to the contents of liquid laundry capsules the ACCC jointly established, with industry, an Australian Industry Guideline for Labelling & Packaging of Liquid Laundry Capsules (ACCC 2015).

International regulatory status

Exposure standards

The following Protective Action Criteria (PAC) –formerly known as Temporary Emergency Exposure Limits (TEELs) – are available for sulfuric acid, monododecyl ester (CAS No. 151-41-7) (Chemwatch n.d.):

- PAC-1 = 3.9 mg/m^3, concentration of the chemical ‘above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience notable discomfort, irritation, or certain asymptomatic,

non-sensory effects. However, these effects are not disabling, are transient and reversible upon cessation of exposure.
- PAC-2 = 43 mg/m^3, concentration of the chemical 'above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience irreversible or other serious, long lasting, adverse health effects or an impaired ability to escape.
- PAC-3 = 260 mg/m^3, concentration of the chemical 'above which it is predicted that the general population, including susceptible individuals, when exposed for more than one hour, could experience life-threatening adverse health effects or death.

As stated by the US Department of Energy (DOE), these values are intended for use until Acute Exposure Guideline Levels (AEGLs), or Emergency Response Planning Guidelines (ERPGs) are adopted for chemicals.

United Nations

These chemicals are not currently identified as persistent organic pollutants (POPs) (UNEP 2001), ozone depleting substances (UNEP 1987), or hazardous substances for the purpose of international trade (UNEP & FAO 1998).

OECD

Of the chemicals in this group, 10 are listed as OECD High Production Volume (HPV) chemicals (OECD n.d.). Together with 12 other substances that are listed as non-HPV chemicals, they have been sponsored for assessment as part of a group of anionic surfactants under the Cooperative Chemicals Assessment Programme (CoCAP). A Screening Information Data Sheet (SIDS) Initial Assessment Report (SIAR) has been published (OECD 2007), that includes all but one of these chemicals. Alkyl sulfates with a chain length of C15-C16 were found to have properties that indicate a hazard for the environment.

Health hazard information

Toxicology information is not available for all chemicals in the group. The chemicals with data have similar physico-chemical and toxicological properties, validating the read across approach within the category. Where information on a toxicity endpoint of some chemicals was not available, information obtained for the other chemicals in the group, or from a structurally similar chemicals, was used as surrogate data. Data has been included for structurally similar alkyl sulfates including salts of lauryl sulfate, that have been previously assessed.

For the chemicals in this evaluation which are UVCBs, the relevant hazard classifications have been determined according to the criteria for mixtures, based on the expected alkyl chain length distribution (UNECE 2017).

Toxicokinetics

Absorption

Following oral administration, alkyl sulfates are well absorbed in rats, dogs and humans. This was indicated by excretion of up to 98% of the dose administered in the urine after oral and intravenous or intraperitoneal application for several alkyl sulfates. In humans, following oral

administration of radiolabelled erythromycin salt of C16 AS, radioactivity in plasma was maximal within 30 minutes to 2 hours, indicating rapid absorption. Hence, oral absorption is assumed to be 100% (REACH n.d.-c; OECD 2007).

Absorption through the skin is expected to be limited, as anionic surfactants tend to bind to the skin surface (Black and Howes 1980). Animal studies indicated low level of percutaneous absorption of alkyl sulfates. Less than 0.4% of a 3 µM dose of the structurally similar C12 AS Na was percutaneously absorbed in guinea pigs, based on recovery of the radiolabel in urine, faeces and expired air (OECD 2007). Early studies with isolated human skin were unable to detect penetration of a homologous series of alkyl sulfates, ranging from C8 to C18 carbon chain lengths (Blank and Gould 1961). Based on experimental data in animals and humans, a default dermal absorption value of 1% is generally assumed for risk assessment of alkyl sulfates (REACH n.d.-a, REACH n.d.-c).

Studies with rats indicated that pre-washing of the skin with surfactant enhanced alkyl sulfate skin penetration (Black and Howes 1980).

Distribution

Tissue disposition studies with C12 AS in rats indicated that 36% of an intravenous dose reached the liver within 15 minutes, followed by the intestine, the kidney and the blood (Greb and Wingen 1980).

Following intraperitoneal injection of radiolabelled alkyl sulfates (potassium salts of C10 AS, C12 AS and C18 AS) in rats, large amounts of the chemicals or their metabolites were detected in the liver and kidneys. The levels (not quantified) were highest 1 hour after application. C10 AS K was cleared from tissues more rapidly than the longer chain alkyl sulfate, C18 AS K. After 6 hours, only traces of the C10 AS K remained in the kidney, whereas it took 12 hours for the C18 AS K to be cleared from the kidney (HERA 2002).

Metabolism

Alkyl sulfates are extensively metabolised in rats, dogs and humans. Omega-oxidation of the alkyl chain followed by beta-oxidation is the postulated mechanism of their degradation. The major metabolite for even-chained alkyl sulfates was identified as the 4-carbon compound, butyric acid 4-sulfate, while 4-butyrolactone and glycolic acid sulfate have also been detected as minor metabolites in urine (OECD 2007). For odd numbered chains (specifically, C11 AS) propionic acid-3-sulfate was the major urinary metabolite and pentanoic acid-5-sulfate and inorganic sulfate were minor metabolites. The C2 fragments enter the C2 pool of the body and are either oxidized to CO_2 or retained in the body. About 10–20% of the dose usually is eliminated as inorganic sulfate (OECD 2007).

Excretion

The major path of excretion of the alkyl sulfates is via the urine. Studies with radiolabelled alkyl sulfates (ranging in chain length from C10 to C18) showed that, irrespective of chain length or counter ion, over 80–90% of the administered dose was excreted in the urine in rats, pigs and humans (Denner et al. 1969; Burke et al. 1975). Lower amounts of the alkyl sulfates are excreted via the faeces within 48 hours of oral administration. Only 1–7.7% of the dose applied was found in the bile, up to 6 hours after intravenous application. After oral administration of 14.4 mg/kg bw of the erythromycin salt of C16 AS to dogs or 250 mg/person to humans, radioactivity in plasma was maximal within 30 minutes to 2 hours of ingestion in both species, indicating rapid absorption (OECD 2007). The plasma concentration declined rapidly afterwards and reached 10% of the maximum concentration after 6 hours, indicating rapid elimination (REACH n.d.-a).

Data show that there are only minor differences for the alkyl sulfates of different chain lengths in the overall excretion. There are also no major differences in overall excretion after oral, intraperitoneal or intravenous application. Comparison of rates of excretion of different chain lengths of alkyl sulfates indicated slower rates of metabolism for longer chain lengths (60% for C10, 40% for C11 and 15% for C18), 6 hours after intraperitoneal. application. However, the rate of excretion of C12 was rapid and completed within 6 hours, indicating faster metabolism of the C12 compound than that of other chain lengths (OECD 2007).

Due to dissociation of these chemicals into alkyl sulfate moiety and counter ions in the body, the counterions are not expected to have significant effect on absorption, distribution, metabolism or excretion of the alkyl sulfates. This is supported by comparable results achieved with alkyl sulfates containing different counterions (HERA 2002).

Acute toxicity

Oral

Based on available data, these chemicals are considered to have low to moderate acute oral toxicity. In general, the LD50 values seemed to decrease with increasing chain lengths (although it is noted that available date indicates C8 AS Na has low acute oral toxicity). Hazard classification is warranted for alkyl sulfates with a chain length C12 and below unless experimental data are available indicating otherwise. For the UVCBs, these effects will depend on the composition of the chemical. Based on the available data the following chain length ranges are considered likely to have moderate acute oral toxicity:

- C6–10 alkyl sulfates (CAS No. 68187-17-7)
- C6–12 alkyl sulfates (CAS No. 90583-25-8)
- C9–11 alkyl sulfates (CAS No. 84501-49-5)
- C9–13 alkyl sulfates (CAS No. 72906-11-7)
- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0)
- coco alkyl sulfates (CAS No. 97375-27-4).

In a good laboratory practice (GLP) compliant acute oral toxicity study conducted in accordance with OECD Test Guideline (TG) 423, 3 female Wistar rats were treated with a single dose of C8 AS Na (CAS No. 142-31-4) at 2,000 mg/kg bw. The reported LD50 was >2,000 mg/kg bw. Reported clinical signs of toxicity included impaired general state, dyspnoea and piloerection from 1–5 hours after administration (REACH n.d.-a).

In a GLP compliant acute oral toxicity study conducted in accordance with EU Method B.1 bis (Acute Oral Toxicity – Fixed Dose Procedure), rats (strains not specified) (5/sex/dose) were treated with single doses of 500 or 2,000 mg/kg bw of C12-14 AS Na (CAS No. 85586-07-8). Mortality was observed in male (5/5) and female (1/5) rats receiving 2,000 mg/kg bw. All animals at this dose showed hunched back, decreases in motor activity, ataxia and pallor. In addition, the males also showed piloerection, and the females hypotonia. No mortality or clinical signs of toxicity were observed at 500 mg/kg bw. The reported LD50 value was between 500 and 2,000 mg/kg bw (REACH n.d.-d).

In a GLP compliant, non-guideline acute oral toxicity study conducted according to Directive 79/831/EEC, Annex V, part B, Wistar rats (5/sex/dose) were administered a single dose of 2,000 mg/kg bw C16–18 AS Na (CAS No. 68955-20-4). The reported LD50 value was

>1,100 mg/kg bw. Clinical signs of toxicity were decreased motility and abnormal salivation in males (REACH n.d.-e).

The following oral LD50 values have been reported in rats and mice for various chain length alkyl sulfates (OECD 2007; CIR 2010):

- between 290 and 1950 mg/kg bw for C10
- between 1,000 and 2,000 mg/kg bw for C10-16 and C12
- greater than 2,000 mg/kg bw for C12-15, C12-16 and C12-18
- greater than 3,000 mg/kg bw/day for C14, C16 and C18
- greater that 5,000 mg/kg bw for C14-18 and C16-18.

The reported oral LD50 values in rats for structurally related chemical, C12 AS Na (CAS No. 151-21-3), were 977–1427 mg/kg bw (NICNAS 2013).

The counter ion does not appear to influence acute oral toxicity in a substantial way. Clinical signs observed were piloerection, lethargy, decreased motor activity and respiratory rate. At necropsy the major findings were signs of irritation in the gastrointestinal tract and pallor in inner organs (OECD 2007).

Dermal

Based on the limited data available, these chemicals do not warrant hazard classification for acute dermal toxicity. Whilst several studies of limited reliability indicate moderate dermal toxicity for analogue chemicals (OECD 2007), the available studies for chemicals in this group indicate low dermal toxicity.

In a GLP compliant acute dermal toxicity study conducted in accordance with OECD TG 402, Wistar rats (5/sex/dose) were treated with a single dose of 2,000 mg/kg bw of C8 AS Na (CAS No. 142-31-4). The reported dermal LD50 value was >2,000 mg/kg bw. No systemic clinical signs were observed during clinical examination. There were no macroscopic pathological findings in the animals euthanised at the end of observation period (REACH n.d.-a).

In a non-GLP compliant acute dermal toxicity study conducted in accordance with OECD TG 402, New Zealand rabbits (3/sex/dose) were treated with a single dose of 2,000 mg/kg bw of C10–16 AS NH_4 (CAS No. 68081-96-9). The reported dermal LD50 values were between 500 and 2,000 mg/kg bw. Severe erythema and slight eschar formation at 24 hours, necrosis by days 2–14 with sloughing of the skin by days 8–14 and hyper-pigmentation of the new skin by day 14 were observed, but no signs of systemic toxicity were reported (REACH n.d.-b).

Other reported LD50 values in rabbits were 200 mg/kg bw for the C12 AS and >500 mg/kg bw for the C12-13 AS and C10-16 AS (OECD 2007). However, no experimental data are publicly available to support hazard classification.

Inhalation

Information on acute inhalation toxicity of alkyl sulfates is not available.

Inhalation of aerosolized solutions of sodium, ammonium and triethanolamine (TEA) salts of C12 alkyl sulfate caused irritation of the respiratory tract in mice. After 2 minutes of exposure, a 50% reduction in respiratory rate occurred at concentrations of 88, 114 and 135 µg/L for

the Na, NH_4 and TEA salts, respectively. Evidence of systemic toxicity was not reported (HERA 2002).

Corrosion/Irritation

No data are available for the alkyl sulfuric acids in this group: 1-hexadecanol, hydrogen sulfate (CAS No. 143-02-2); sulfuric acid, monooctadecyl ester (CAS No. 143-03-3); and sulfuric acid, monododecyl ester (CAS No. 151-41-7). These long chain monoesters have similar acidic pKa values (approximately -3, calculated). Based on the strong acidic nature, these chemicals are expected to be corrosive to skin and cause serious eye damage.

Skin irritation

Based on the available data these chemicals are irritating to skin with varying degrees of severity. There are limitations in the available studies including test substances with variable purity and composition and inconsistencies in the reporting of effects. However, the available data indicate that the severity of effects generally decrease with increasing chain length.

In animal studies there is evidence of destruction of skin tissue following 4-hour exposure for alkyl sulfates containing C8 and C10 chain lengths, warranting hazard classification. The corrosive nature of these chemicals is also supported by in vitro data. In the absence of information, corrosivity is also expected for C6 and C9 alkyl sulfates. For the UVCBs, effects will depend on the composition. The following UVCB substances are expected to contain at least 5% of alkyl sulfates with C6, C8 C9 and/or C10 chain lengths, warranting the same hazard classification. Available data support this classification for:

- C6–10 alkyl sulfates (CAS No. 68187-17-7)
- C6–12 alkyl sulfates (CAS No. 90583-25-8)
- C9–11 alkyl sulfates (CAS No. 84501-49-5)
- C9–13 alkyl sulfates (CAS No. 72906-11-7)
- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- coco alkyl sulfates (CAS No. 97375-27-4).

The weight of evidence for alkyl sulfates with carbon chains of C12 to C15 suggests that these are moderate to severe irritants but with limited reported incidence of necrosis, warranting hazard classification as irritants not corrosives. For the UVCBs, effects will depend on the composition. The following UVCB substances are expected to contain at least 10% of alkyl sulfates with C12, C13, C14 and/or C15 chain lengths (but not greater than 5% ≤C10), warranting the same hazard classification. Available data support this classification for:

- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0)
- C12–14 alkyl sulfates (CAS No. 85586-07-8; 85681-66-9; 90583-16-7; 90583-18-9; 90583-23-6)
- C12–15 alkyl sulfates (CAS No. 68815-25-8; 68890-70-0)
- C12–16 alkyl sulfates (CAS No. 73296-89-6; 85252-21-7)
- C12–18 alkyl sulfates (CAS No. 68955-19-1, 90583-13-4).

Alkyl sulfates with carbon chains of C16 to C18 are slightly irritating to skin at tested concentrations. There are no experimental data available for C20 alkyl sulfates; however, the C20 alkyl sulfate (CAS No. 13177-49-6) is predicted to be non-irritating to skin using OASIS–

TIMES (Optimised Approach based on Structural Indices Set–Tissue Metabolism Simulator; version 2.8.1). Therefore, C20 alkyl sulfates are expected to be at most slightly irritating.

Consistent with the surfactant properties, alkyl sulfates produce dermal effects in a dose dependent manner, with increasing concentration resulting in increased severity of effects. Based on human data (see **Observation in humans**) minimal irritation is expected at concentrations <1%.

Alkyl chain length (C6, C8, C9, C10)

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, 3 New Zealand White rabbits (NZW) (sex not specified) were treated with 0.5 g C8 AS Na (purity 92.5%) (CAS No. 142-31-4) moistened with water for 4 hours under semi-occlusive conditions. Observations were recorded at 1, 24, 48, 72 hours and 14 days after patch removal. The following mean scores were reported for observations at 24, 48 and 72 hours for each animal: 3.0, 3.0 and 3.0 for erythema and 2.0, 3.3 and 3.0 for oedema. Signs of irritation included scaling, eczema-like skin lesions, erythema and oedema at and beyond the application site, bloody/yellowish discoloured lesions at the application site. These effects were not reversible in all animals during the course of the study (REACH n.d.-s).

In a GLP compliant study conducted in accordance with OECD TG 404, Kleinrussen, Chbb:HM rabbits were treated with C8–14 AS NH4 (CAS No. 90583-10-1) (32.9 % in water) for 4 hours under semi-occlusive conditions. Observations were recorded at 24, 48, 72 hours and 21 days after patch removal. Mean scores for observations at 24, 48 and 72 hours were reported to be ≥2 for erythema and oedema (individual scores not reported). All effects persisted up to 21 days after application. The test material was concluded to be corrosive although no details of effects were reported (OECD 2007).

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, Kleinrusse, Chbb:HM, rabbits (sex and number not specified) were treated with C10 AS Na (CAS No. 142-87-0) (purity 29%) for 4 hours under semi-occlusive conditions. Observations were recorded at 24, 48, 72 hours and 21 days after patch removal. The following mean scores were reported for observations at 24, 48 and 72 hours: 3.3 for erythema and 2.7 for oedema respectively (maximum score of 4). Erythema was observed which was not fully reversible within the 21 day observation period. Necrosis was observed from day 2. The test material was concluded to be corrosive on the basis of this study (REACH n.d.-a).

In a GLP compliant study conducted in accordance with OECD TG 404, Kleinrussen, Chbb:HM rabbits were treated with the structurally related chemical, C8–16 AS Na (CAS No. 90583-27-0) (29–31 % in water) for 4 hours under semi-occlusive conditions. Observations were recorded at 24, 48, 72 hours and 21 days after patch removal. Mean scores for observations at 24, 48 and 72 hours were reported to be ≥2 for erythema and oedema (individual scores not reported). After 21 days the scars on the skin in all animals were observed. The test material was concluded to be corrosive in this study (OECD 2007).

In a GLP compliant in vitro skin corrosion assay conducted in accordance with OECD TG 431, C8 AS Na (CAS No. 142-31-4) was applied to reconstructed human epidermis (EpiDermTM) for 3 and 60 minutes. The mean tissue viability was 91 and 5 after 3 and 60 minutes, respectively. These results warrant a UN GHS skin corrosive category 1B/1C hazard classification based on the test method prediction model criteria (≥ 25% after 3 min exposure AND <15% after 60 min exposure) (REACH n.d.-s).

In a GLP compliant in vitro skin irritation study conducted in accordance with OECD TG 439 (in vitro reconstructed human epidermis (RhE) test method for skin irritation), C8 AS Na

(CAS No. 142-31-4) was applied to RhE. Although some experimental details are not available, a mean tissue viability value of 2% was reported and it was determined to be at least irritating to the skin. Interpretation of results obtained from OECD TG 439 studies do not allow for distinction between irritation and corrosion (REACH n.d.-s). Although an additional study conducted according to OECD TG 435 would normally enable a definitive classification, there is uncertainty on the acid/alkaline reserve which impacts the conclusion of the study (see below).

In a GLP compliant in vitro skin corrosion study conducted in accordance with OECD TG 435 (in vitro membrane barrier test method for skin corrosion), 300 mg of C8 AS Na (CAS No. 142-31-4) was applied to the membrane barrier in quadruplicate. The chemical was stated to have a low acid/alkaline reserve (category 2). No details were provided. The mean time to break through the membrane and subsequently activate the underlying chemical detection system (CDS) was >60 minutes. Based on the test method prediction model criteria, the chemical was determined to be non-corrosive to skin, however the acid/alkaline reserve could not be verified (REACH n.d.-s).

In a GLP compliant in vitro skin corrosion study conducted in accordance with OECD TG 435 (in vitro membrane barrier test method for skin corrosion), 500 mg of C10 AS Na (CAS No. 142-87-0) was applied to the membrane barrier in quadruplicate. The chemical was stated to have a high acid/alkaline reserve (category 1). The mean time to break through the membrane and subsequently activate the underlying CDS was 61.33 ± 4.7 minutes. Based on the test method prediction model criteria, the chemical was determined to be corrosive to skin, however the acid/alkaline reserve could not be verified (REACH n.d.-a).

Alkyl chain length (C12, C13, C14, C15)

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, NZW rabbits (n=3, sex not specified) were treated with 0.5 g (purity 88.7%) of C12-18 AS (CAS No. 68955-19-1) for 4 hours under semi-occlusive conditions. Observations were recorded at 1, 24, 48 and 72 hours after patch removal. Only the mean score of all 3 rabbits were reported. The mean scores were 3/4 for erythema and 2.3/4 for oedema. Both the erythema and oedema were fully reversible within 14 days (REACH n.d.-r; NICNAS 2013).

In a skin irritation study described as being GLP compliant and in accordance with OECD TG 404, Kleinrusse Chbb:HM male rabbits (n=5) were treated with 0.5 mL (neat) of C12-14 AS Mg (CAS No. 90583-23-6) (purity not reported) for 4 hours under occlusive conditions. Observations were recorded at 1, 24, 48 and 72 hours and 21 days after patch removal. Only the mean score of all 3 rabbits were reported. The mean scores were 4/4 for erythema and 4/4 for oedema. The effects were fully reversible within 21 days (OECD 2007; REACH n.d.-h).

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, rabbits (n=3, sex or strain not specified) were treated with a 30% solution in water (purity 90%) of C12–14 AS Na (CAS No. 85586-07-8) for 3 min, 1 or 4 hours. Effects after the 3 min exposure included slight erythema and brown discolouration. Effects after the 1 hour exposure included slight to moderate erythema, intensive growth of hair and thickening of the skin. The mean scores (all rabbits) after 4 hour exposure were 2.3 and 3.0 for erythema and oedema, respectively. Necrosis and eschar were observed after 7 days in animals exposed for 4 hours. Brown discoloration, intensive growth of hair and slight erythema being observed after 21 days. The effects were not reversible within 21 days (OECD 2007; REACH n.d.-d).

In a skin irritation study reported to be similar to OECD TG 404, rabbits (n=5, sex or strain not specified) were treated with C12-14 AS TEA (90583-18-9) at a dose level of 25% for

4 hours. Mean erythema for the test animals over three scoring time points (24, 48 and 72 hours) was 3.7. Mean oedema was 2.1 (HERA 2002).

In a skin irritation study reported to be similar to OECD TG 404 (but with prolonged exposure period), NZW rabbits (n=3, sex not specified) were treated with a 30% solution of C12–14 AS Na (CAS No. 85586-07-8) for 24 hours under occlusive conditions. Observations were recorded at 1, 24, 48 and 72 hours after patch removal. The mean scores (of the 24, 48 and 72 hours observations) for erythema for the 3 rabbits were reported as, 3, 0.67 and 3. No oedema were observed. The erythema was not reversible in any of the animals within 72 hours (REACH n.d.-d).

In a skin irritation study described as being GLP compliant and in accordance with OECD TG 404, NZW rabbits (n=3, sex not specified) were treated with 0.5 mL of C12-16 AS Na (CAS No. 73296-89-6) (30% solution) for 4 hours under semi-occlusive conditions. Observations were recorded at 1, 24, 48 and 72 hours after patch removal. Only the mean score of all 3 rabbits were reported. The mean scores were 3/4 for erythema and 3/4 for oedema. The erythema was not fully reversible within 14 days; however, the oedema was (REACH n.d.-g).

The structurally related chemical, C12 AS Na (CAS No. 151-21-3) was reported to be irritating to the skin of rabbits, producing erythema and oedema on unabraded rabbit skin after a 4 hour application of a 5–25% solution (NICNAS 2013).

In a skin irritation similar to OECD TG 404, Kleinrusse, Chbb:HM, rabbits were treated with 0.5 mL (neat) C12 AS Na (CAS No. 151-21-3) for 24 hours under occlusive conditions. Observations were recorded at 24 and 72 hours after patch removal. The mean scores were 2.2/4 and 1.7/4 for erythema and oedema, respectively. The effects were not fully reversible within 72 hours (REACH n.d.-b).

In a skin irritation study reported to be similar to OECD TG 404, rabbits (n=5, sex or strain not specified) were treated with C12 AS Na (CAS No. 151-21-3) at a dose level of 25% for 4h. Mean erythema for the test animals over three scoring time points (24, 48 and 72 hours) was 2.0. Mean oedema was 0.7 (HERA 2002).

Alkyl chain length (C16, C18, C20)

In a skin irritation study conducted in accordance with OECD TG 404, Kleinrusse Chbb:HM rabbits (n=5, sex not specified) were treated with 0.5 g C16-18 AS Na (purity 55%) (CAS No. 68955-20-4) for 24 hours under occluded conditions. Observations were recorded at 24, 48 and 72 hours after patch removal. The overall mean scores (of the 24, 48 and 72 hours observations) were 1.3 for erythema and 0.6 for oedema. Both observations were fully reversible within 7 days (REACH n.d.-e).

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, Kleinrusse Chbb:HM rabbits (n=5, sex not specified) were treated with 0.5 mL (25%, purity 94.3%) of C16-18 AS Na (CAS No. 68955-20-4) for 4 hours under occlusive conditions. Observations were recorded at 24, 48 and 72 hours after patch removal. Only the mean score of all 3 rabbits were reported. The mean scores were 1.6/4 for erythema and 0.7/4 for oedema. Both the erythema and oedema were fully reversible within 21 days (REACH n.d.-e).

The skin irritation potential of an undiluted mixture of C16 AS Na (CAS No. 1120-01-0) and C18 AS Na (CAS No. 1120-04-3) was evaluated by the Draize method using 6 albino New Zealand rabbits. The mean irritation scores at 24 and 72 hours were averaged to calculate a primary irritation index of 0.8, indicating slight irritation (CIR 2010).

In a non-GLP compliant in vitro skin corrosion assay conducted in accordance with OECD TG 431, C16-18 AS Na (CAS No. 68955-20-4) (25%, pH 7) was applied to reconstructed human epidermis (EpiDermTM) for 3 and 60 minutes. The mean tissue viability was 103 and 107 after 3 and 60 minutes, respectively. Because cell viability was not reduced the chemical was not considered to be corrosive (REACH n.d.-e).

In a non-GLP compliant in vitro skin irritation study conducted in accordance with OECD TG 439 (in vitro reconstructed human epidermis (RHE) test method for skin irritation), C16-18 AS Na (CAS No. 68955-20-4) was applied to RhE, for an exposure period of 1 hour, followed by an observation period of 42 hours. A mean tissue viability value of 117% was reported for the chemical in this study, and it was determined to not be irritating to the skin (REACH n.d.-e).

Eye irritation

Based on the weight of evidence across this group of chemicals and structurally similar alkyl sulfates, the majority of these chemicals are expected to cause serious eye damage, warranting hazard classification. For the UVCBs, effects will depend on the composition. UVCB substances (except CAS No. 68955-20-4) are expected contain at least 3% of alkyl sulfates with chain lengths less than C15, warranting the same hazard classification. This is supported by the available data.

The available data indicates that alkyl sulfates with carbon chains of C16 to C18 including the UVCB, CAS No. 68955-20-4, cause less severe effects, although severity of effects are still sufficient to warrant classification as an eye irritant.

Alkyl chain length (C6, C8, C9, C10)

No reliable data are available. Chemicals that are corrosive are expected to cause irreversible damage to eyes.

Alkyl chain length (C12, C13, C14, C15)

Irreversible eye damage was reported in several eye irritation studies conducted according to OECD TG 405.

In a GLP compliant eye irritation study conducted in accordance with OECD TG 405, 0.1 mL of C12-18 AS Na (CAS No. 73296-89-6) (purity 30%) was instilled into one eye each of 3 NZW rabbits. Observations were recorded at 24, 48 and 72 hours. The following mean scores based on observations at 24, 48 and 72 hours were reported: corneal opacity 1/4, iritis 2/2, conjunctival redness 2/3 and chemosis 3.6/4. The observed effects (except chemosis) were not reversible in all animals within 21 days (REACH n.d.-g). In a separate study investigating effects at different concentrations, the chemical cause irreversible damage at concentrations ≥10%, moderate irritation at 5% and no irritation at 1% (OECD 2007).

In an eye irritation study conducted in accordance with OECD TG 405, 0.1 mL of C12-16-AS Na (CAS No. 73296-89-6) (30% purity) was instilled into the conjunctival sac of one eye each of NZW rabbits (n=3, sex not specified). Observations were recorded at 24, 48, 72 hours, and at 6 days. The following mean scores were reported for the 24, 48 and 72 hour observations: corneal opacity score of 1 (out of 4), iritis score of 0.2 (out of 2), conjunctival score of 2.8 (out of 3), and chemosis score of 3.6 (out of 4). The observed effects were not reversible in any of the animals within 6 days (REACH n.d.-g).

In a non-GLP compliant eye irritation study conducted in accordance with OECD TG 405, 0.1 mL of 10% C12–14 AS Mg (CAS No. 90583-23-6) solution in water was instilled into the conjunctival sac of one eye each of 4 male Kleinrusse Chbb:HM rabbits. Observations were recorded at 1, 24, 48, 72 hours, and at 7, 14 and 21 days. The following mean scores were reported (based on observations at 24, 48 and 72 hours): corneal opacity scores of 1 out of 4 for all animals, iritis (no data), conjunctival redness scores of 2, 2, 2.3 and 2.3 (out of 3), and chemosis scores of 0.7, 0.7, 1 and 1.3 (out of 4). Corneal opacity score remained as 1 after 21 days (considered non-reversible), and conjunctival blood infiltration was observed in one rabbit after 14 days and was still observed at 21 days (REACH n.d.-h).

In a GLP compliant eye irritation study performed with rabbits in accordance with OECD TG 405, C12-14 AS TEA (CAS No. 90583-18-9) (25% in water) effects in the cornea and conjunctivae did not reverse in 21 days (OECD 2007).

In a non-GLP compliant eye irritation study conducted in accordance with OECD TG 405, 0.1 mL of the structurally related chemical, C12 AS Na (CAS No. 151-21-3) (purity not reported) was instilled into one eye each of 4 Kleinrusse rabbits. Observations were recorded at 24, 48 and 72 hours. The following mean scores were reported at 24, 48 and 72 hours: corneal opacity 1/4, iritis 0/2, conjunctival redness 2.6/3 and chemosis 1.1/4. The observed effects (corneal opacity and conjunctival redness) were not reversible in all animals within 21 days (REACH n.d.-b).

The structurally related chemical, sodium lauryl sulfate (C12 AS Na) (CAS No. 151-21-3) (at 25%) caused irreversible effects in the eye within the observation period of 21 days (NICNAS 2013).

In a GLP eye irritation study performed with rabbits in accordance with OECD TG 405, with the structurally related, C12-16 AS NH4 (CAS No. 90583-12-3) (30% in water), effects in the cornea and conjunctivae did not reverse in 21 days (OECD 2007).

Alkyl chain length (C16, C18, C20)

In a GLP compliant eye irritation study performed in accordance with OECD TG 405, 0.1 mL of 25% C16-18 AS Na (CAS No. 68955-20-4) in water was instilled into the conjunctival sac of one eye each of 4 male Kleinrusse Chbb:HM rabbits. The following mean scores based on observations at 24, 48 and 72 hours were reported: corneal opacity 0.8/4, iritis 0/2, conjunctival redness 2.3/3 and chemosis 0.4/4. The observed effects were reversible in all animals within 7 days (OECD 2007; REACH n.d.-e). In separate studies with the chemical at 5%, moderate eye irritation that was reversible within 12 days was reported (OECD 2007).

In 2 ex vivo eye corrosivity/irritation studies, conducted according to OECD TG 437 (Bovine corneal opacity and permeability test, BCOP), C16–18 AS Na (CAS No. 68955-20-4), 2–20% was considered non-corrosive based on the criteria of the test. The in vitro irritancy score (IVIS) was reported to be ≤3 (REACH n.d.-e).

In a third OECD TG 437 study, the mean IVIS was 73 at 20% of C16–18 AS Na (CAS No. 68955-20-4) (IVIS >55 is regarded as serious eye damage); however, there was a deviation from the guideline. The incubation time was 4 hours instead of 10 min as recommended for liquids and surfactants (REACH n.d.-e).

In an in vitro reconstructed human Cornea-like Epithelium (RhCE) test conducted according to OECD TG 492 (EpiOcular™EIT) with the chemical (20% in water) the mean tissue viability was 87.6. Based on the prediction model criteria, the test chemical is identified as not requiring classification and labelling according to UN GHS (No Category) (REACH n.d.-e).

In another in vitro RhCE test based on draft proposal for OECD TG 492 (EpiOcular™EIT) with the chemical undiluted and at 25% (in water) the mean tissue viability was 25 and 63 respectively. Based on the prediction model criteria, no prediction can be made for the undiluted chemical but the chemical at 25% is identified as not requiring classification and labelling according to UN GHS (No Category) (REACH n.d.-e).

Respiratory irritation

Limited data are available. Given the irritant properties of these chemicals, inhalation could lead to irritation/corrosion of the mucous membranes of the respiratory tract. Inhalation of aerosolised solutions of sodium, ammonium and triethanolamine (TEA) salts of C12 alkyl sulfate caused irritation of the respiratory tract in mice (see **Acute oral toxicity – inhalation**).

Observation in humans

To investigate the irritant potential of sodium salts of n-alkyl sulfates with different carbon chain length (C8, C12, C14) on human skin, Nardo et al (1998) applied 0.2% solution (w/v) of these substances on the anterior forearm of 10 healthy human volunteers aged 24 to 35 years (details of application method not provided). Evaluations were performed at baseline, 24, 48 and 72 hour, and erythema, transepidermal water loss (TEWL) and skin hydration were estimated. TEWL was reported to increase at 24 hours with all 3 substances: sodium lauryl sulfate (C12) showed the highest increase, followed by octyl (C8) and tetradecyl sulfate (C14). Skin hydration was reduced following application of the 3 substances, and a slight increase in redness was reported.

Several human patch studies have been conducted for assessing skin irritation of alkyl sulfates in humans (Griffiths et al. 1997; Robinson et al. 1998; Basketter et al. 2004). In these studies, 20% C12 AS Na has been consistently shown to cause irritation in humans. In most human repeated 4-hour patch tests, 20% C12 AS Na is routinely used as the positive control material (as a material well documented to produce an irritation response under occlusive patch conditions) (OECD 2007).

In skin irritation studies in humans, alkyl sulfates are reported to be moderate to strong skin irritants at concentrations of 10% or greater, and slightly irritating at 1% (HERA 2002).

In two skin irritation studies in humans, with a mixture of C16 AS Na (CAS No. 1120-01-0) and C18 AS Na (CAS No. 1120-04-3), skin irritation effects were not produced at concentration of 0.4% (CIR 2010). No skin irritation was reported in human volunteers when structurally related chemical, C12 AS Na (CAS No. 151-21-3) (1%) was applied repeatedly to the skin (HERA 2002).

A range of skin irritation effects were reported in several studies of C12 AS TEA (CAS No. 139-96-8). In a human skin irritation study, a 10% solution of C12 AS TEA (vehicle not provided) at neutral pH was applied to the to the forearm of 10 subjects using a Duhring chamber for 5 days. Intense erythema was reported in nearly all subjects when testing was terminated on day 4. In an occlusive patch test, a diluted shampoo containing 4.4% C12 AS TEA was highly irritating in a 21-day cumulative irritation test. No irritation effects were reported in clinical studies when shampoos containing 0.15—10.5% C12 AS TEA was applied under semi-occlusive conditions (CIR 2013).

Sensitisation

Skin sensitisation

Based on the available data these chemicals are not expected to be skin sensitisers. Alkyl sulfates were not skin sensitisers in animal studies. In humans, the sensitising potential was found to be very low.

In a GLP-compliant guinea pig Maximisation test (GPMT) conducted in accordance with OECD TG 406, intradermal induction was performed on 10 guinea pigs (strain and sex not specified) using 0.08% C12 –14 AS Na (CAS No. 85586-07-8). Challenge application with 0.5% or 1% of the chemical in water did not result in skin reactions (REACH n.d.-d). A GPMT with 5% and a Buehler test with 12.5% C12–14 AS Na (CAS No. 85586-07-8) did not give any skin reaction in test animals (animal species not specified) (HERA 2002).

In a Buehler skin sensitisation test, conducted in accordance with OECD TG 406, intradermal induction was performed on 20 female Dunkin-Hartley guinea pigs with 12.5% C12–18 AS Na (CAS No. 68955-19-1 (reported as a read across source for sulfuric acid, mono-C12-16-alkyl esters, sodium salts; CAS No. 73296-89-6). Challenge application with 6.25% of the chemical in water did not result in any skin reactions, 24 or 48 hours after challenge (REACH n.d.-g).

In a similar GPMT, only 2 out of 20 Pirbright white guinea pigs developed slight oedema when challenged with 1% C12-14 AS Mg (CAS No. 90583-23-6) following induction with 0.1% (intradermal) and 2.5% (topical) of the chemical in water (REACH n.d.-h).

In a GLP compliant GPMT, intradermal induction was performed in guinea pigs (n=20, sex not specified) using 5% C16-18 AS Na (CAS No. 68955-20-4) (55% purity). Only slight redness was noticed 24 hours (first reading) and 48 hours (second reading) after challenge application. The chemical was reported to be non-sensitising in this study (REACH n.d.-e). Very few experimental details were available.

In a non-guideline study (Landsteiner Test) induction (25%) and challenge (1%) with C16–18 AS Na (CAS No. 68955-20-4) did not produce any reaction in female Pirbright white guinea pigs (REACH n.d.-e). The Landsteiner test is considered to have limitations, particularly in its ability to detect many known weak to moderate human sensitisers (Horton et al. 1981).

The structurally related chemical, C12 AS Na (CAS No. 151-21-3) is not considered to be a skin sensitiser (NICNAS 2013). While equivocal results were reported in an local lymph node assay (LLNA) (HERA 2002), this was discounted and considered to be a false positive result that skin irritants normally elicit in LLNA. The observed increase in cell proliferation was concluded to be caused by a non-antigen-specific proliferative stimulus induced by the irritating effect of the tested concentrations (4, 5, 10 or 25%).

Observation in humans

These chemicals are not considered to be skin sensitisers in humans (OECD 2007; NICNAS 2018; HERA 2002). There have been rare reports of human subjects reacting to diagnostic patch tests with C12 AS Na (NICNAS 2013). The chemical was reported to have caused considerable irritation but no sensitisation. The known irritancy potential of high concentrations of alkyl sulfates can easily confound the reading of diagnostic patch tests. 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).

In silico data

No structural alerts for skin sensitisation are identified for the parent chemicals in this group in OECD Toolbox version 4.5. Simulation of metabolism (skin metabolism) indicates that aldehyde metabolites of some of the chemicals have a theoretical capacity to bind proteins (OECD 2022). The chemicals are predicted to be non-sensitising using OASIS–TIMES (version 2.31) and DEREK (Deductive Estimation of Risk from Existing Knowledge) Nexus (version 6.0.1) (Lhasa Limited).

Repeat dose toxicity

Oral

Based on the available information, these chemicals are not expected to cause serious systemic health effects following repeated oral exposure.

In a sub-chronic 28 day oral repeat dose toxicity study, conducted according to OECD TG 407, C12–14 AS TEA (CAS No. 90583-18-9, 40% purity) was administered to male and female rats (strain and number of animals in test groups not specified) via gavage at 70, 250 or 750 mg/kg bw/day for 28 days. Limited information was reported with critical systemic effects not specified. Any histopathological changes found in animals dosed at 250 mg/kg bw/day and above were considered directly related to the irritating potential of the test substance. Examination of the adrenals gave no evidence of inflammation or ulcer due to stress. At 750 mg/kg bw, gastric irritation was observed and animals showed leucocytosis. The no observed adverse effect level (NOAEL) was considered to be 250 mg/kg bw (REACH n.d.-i).

In a 13 week study, conducted according to OECD TG 408, SD rats (20/sex/dose) were administered C16–18 AS Na (CAS No. 68585-47-7) in diet at 0.25, 0.5 and 1%, equivalent to 0, 55.5, 112 and 201 mg/kg bw/day for females and 60, 123 and 255 mg/kg bw/day, for males. No treatment related effects were observed in ophthalmoscopic examination, urinalysis, hematology, clinical chemistry, organ weights, gross pathology and histopathology parameters at any dose level compared to control animals. A NOAEL of 1% in diet (equivalent to 201 and 254 mg/kg bw/day for male and female rats, respectively) was established in this study (REACH n.d.-a).

In a similar 13 week study, conducted according to OECD TG 408, Wistar rats (10/sex/dose) were administered C10–16 AS Na (CAS No. 68955-20-4) in diet at 0.07, 0.14, 0.28, 1.13 or 2.25% (61, 123, 230, 482, 970 and 2067 mg/kg bw/day). Only adaptive changes (elevated liver weights due to hypertrophy) were observed at 970 mg/kg bw/day and above. The established NOAEL in this study was 482 mg/kg bw/day (REACH n.d.-a).

Similar results were obtained with C12–15 AS Na (CAS No. 68890-70-0). When administered to Colworth Wistar-derived rats (10/sex/dose) at 0.07, 0.14, 0.28, 1.13 or 2.25% (equivalent to 58, 113, 228, 470, 961 and 1944 mg/kg bw/day for males, and 66, 131, 261, 506, 1070 and 2218 mg/kg bw/day for females, respectively) for 13 weeks (OECD TG 408), only adaptive changes in liver were observed. The NOAEL was established as 1.13% (calculated to be 488 mg/kg bw/day for males and females) based on only adaptive changes in the liver observed at this dose level (REACH n.d.-d).

Other studies (OECD 2007; NICNAS 2013) have reported that following repeated oral exposure to alkyl sulfates with chain lengths between C12 and C18, the liver was the only target organ for systemic toxicity. Adverse effects included an increase in liver weight, enlargement of liver cells, and elevated levels of liver enzymes. The lowest observed adverse effect level (LOAEL) for liver toxicity (parenchymal hypertrophy and increase in relative liver weight) was 230 mg/kg bw/day for C16–18 AS Na in a 13-week dietary study in rats.

Dermal

Based on the limited studies available, these chemicals are not likely to cause serious systemic effects following repeated dermal exposure. However, due to their skin irritating effect, these chemicals may compromise the integrity of the skin and increase dermal absorption of other chemicals present in product formulations. Necrosis and ulceration of the skin were noted in test animals following long term exposure (HERA 2002).

In a non-guideline 21 day dermal repeat exposure study, conducted similarly to OECD TG 410, mice (3/sex/dose) (strain not specified) were treated dermally twice weekly with 5, 10, 15 or 18% C12–15 AS Na (CAS No. 68890-70-0) for 21 days. All mice in the highest dose group died due to dehydration caused by fluid loss through skin lesions. At the 10% concentration, oedema, hyperkeratosis and acanthosis of the epidermis were observed at the site of application. These effects were dose related and severe at 15%, including ulceration and necrosis with inflammatory exudate in animals that died. Epidermal thickening due to hyperkeratosis and acanthosis was also observed in surviving animals. The results were consistent with severe irritant properties of the surfactants. There were no systemic histopathological changes on other organs or tissues (HERA 2002).

In a non-guideline 90 day repeat dose dermal toxicity study conducted similar to OECD TG 411, C57BL mice (10/sex/dose) were administered C12–15 AS Na (CAS No. 68890-70-0) by dermal application. The chemical (0.2 mL) at 5, 10, 12.5 or 15% in solution in water (w/w) (corresponding to 200, 400, 500 and 600 mg/kg bw/day, respectively) was applied dermally twice weekly for 13 weeks. One mouse treated with 500 mg/kg bw/day died after one week due to dehydration. Absolute and relative kidney weights and relative liver weights were increased in both sexes at 600 mg/kg bw/day. Extensive ulceration and necrosis of the epidermis of the animal that died were observed at 500 mg/kg bw/day, and dose related ulceration of the epidermis with inflammatory exudate were observed at the two highest dose levels. The NOAEL was determined to be 400 mg/kg bw/day, based on necrosis and ulceration of the skin and changes in organ weights at higher doses (REACH n.d.-d).

In a 90 day repeat dose dermal toxicity study, identical to the procedure described above, C12–14- AS Mg (CAS No. 90583-23-6), caused necrosis and ulceration of the skin, changes in haematology and organ weights (heart, liver and kidney) in male and female C57BL mice. The NOAEL was established at 400 mg/kg bw/day (REACH n.d.-h).

Inhalation

No data are available for these chemicals or structurally similar alkyl sulfates.

Genotoxicity

Alkyl sulfates are not considered to be genotoxic based on available in silico, in vitro and in vivo data. Alkyl sulfates of various chain lengths were not mutagenic in standard bacterial and mammalian cell systems. In vivo studies (micronucleus assay, chromosome aberration

test, and dominant lethal assay) did not give any indication for genotoxic potential of alkyl sulfates.

In vitro

Negative results were reported in bacterial reverse mutation assays (OECD TG 471) in various *Salmonella typhimurium* strains (TA 98, TA 100, TA 1535, TA 1537 and TA 1538) with and without metabolic activation (S9) at concentrations up to 5,000 µg/plate (OECD 2007) for respective chemicals:

- C8 AS Na (CAS No. 142-31-4)
- C10 AS Na (CAS No. 142-87-0)
- C8–14 AS TEA (CAS No. 85665-45-8)
- C8–14 AS NH4 (CAS No. 90583-10-1)
- C8–16 AS Na (CAS No. 90583-27-0)
- C8–18-AS Mg, compounds with TEA (CAS No. 85586-38-5)
- C12 AS TEA (CAS No. 139-96-8)
- C12–14 AS NH4 (CAS No. 90583-11-2)
- C12–14 AS TEA (CAS No. 90583-18-9)
- C12–14 AS Mg (CAS No. 90583-23-6)
- C12–14 AS Na (CAS No. 85586-07-8)
- C12-14 AS MEA (CAS No. 90583-16-7)
- C12-15 AS Na (CAS 68890-70-0)
- C12–16 AS Na (CAS No. 73296-89-6)
- C14 AS Na (CAS No. 1191-50-0)
- C16 AS Na (CAS No. 1120-01-0)
- C16–18 AS Na (CAS No. 68955-20-4).

Negative results were obtained in mammalian cell gene mutation studies (OECD TG 476) in mouse lymphoma L5178Y cells at concentrations up to 1 µL/mL, with and without metabolic activation (OECD 2007) for:

- C14 AS Na (CAS No. 1191-50-0)
- C16 AS Na (CAS No. 1120-01-0).

The structurally related chemical, C12 AS Na (CAS No. 151-21-3) was negative in bacterial reverse mutation assays (OECD TG 471) and a mouse lymphoma cell forward mutation assay (OECD TG 476) (NICNAS 2013).

In vivo

No indications for genotoxic potential of alkyl sulfates were observed in various in vivo studies in rodents (micronucleus assay, chromosome aberration test, and dominant lethal assay).

In a GLP compliant mammalian erythrocyte micronucleus test conducted according to OECD TG 474, CFWI mice (7 animals/sex) were administered C16–18 AS Na (CAS No. 68955-20-4) as a single dose by gavage at 400, 2,000 or 4,000 mg/kg bw. There were no significant increases in the incidence of micronuclei in polychromatic erythrocytes, indicating a lack of clastogenic activity (OECD 2007; REACH n.d.-e). Similar results were obtained with C12–14 AS TEA (CAS No. 90583-18-9) (OECD 2007; REACH n.d.-i).

In a non-GLP compliant mammalian bone marrow chromosome aberration test, similar to OECD TG 475, rats (6 animals/sex) (strain not specified) were fed 1.13% C12–15 AS Na (CAS No. 68890-70-0) in diet for 90 days. No chromosomal aberrations were observed in their bone marrow (REACH n.d.-b).

In a non-GLP compliant dominant lethal mutation assay, similar to OECD 478, 15 male mice (strain not specified) were administered single doses of 210, 980 or 3050 mg/kg bw C12–15 AS TEA Na (CAS No. 68815-70-0) Details of dosing method, mating periods or embryo examination were not provided. No effect on live implants or early or late embryonic deaths were reported (HERA 2002; OECD 2007).

The structurally related chemical, C12 AS Na (CAS No. 151-21-3) was negative in a dominant lethal study using mice (OECD TG 478) (NICNAS 2013).

In silico

No structural alerts for Ames mutagenicity are identified for the parent chemicals in this group. Simulation of metabolism (rat liver S9) indicates that aldehyde metabolites of some of the chemicals have a theoretical capacity to bind DNA in OECD QSAR Toolbox version 4.5 (OECD 2022). The chemicals are predicted to be Ames negative using OASIS–TIMES version 2.31 and DEREK Nexus (version 6.0.1) (Lhasa Limited).

Carcinogenicity

Based on the limited studies available, these chemicals are not expected to be carcinogenic.

In 2 separate non-GLP compliant combined chronic toxicity/carcinogenicity studies, conducted similar to OECD TG 453, 2 batches of C12–15 AS Na (CAS No. 68890-70-0) of slightly different chain length distribution were administered to Wistar rats in their diet. The chemical was administered to rats at 0.015, 0.15 or 1.5% in the diet (equivalent to 11, 113 and 1125 mg/kg bw/day). Each dose group had 45 animals/sex, and the dosing period was 2 years. There were no chemical related mortalities. There was no increase in tumour incidence, nor any impact on tumour type in either study. The chemical (with either chain length distribution) was not tumourigenic at the any dose level, including the highest dose of 1.5% (OECD 2007; REACH n.d.-d).

In a 2 year dermal repeat dose study with few experimental details provided, 0.5% and 10% C12–15 AS was applied to the skin (skin painting) of mice (50/sex/dose, strain not specified) twice weekly, for 2 years. No tumorigenic activity was reported (HERA 2002).

Reproductive and development toxicity

Reproductive toxicity

Based on the limited data available, these chemicals are not expected to cause specific adverse effects on fertility or development following oral exposure.

In a study with limited experimental details available, male Swiss albino mice (10 animals/dose) were given the structurally related chemical C12 AS Na, either at 1% concentration (1,000 mg/kg bw/day) in diet for 2 weeks, or 0.1% for 6 weeks to ensure germ cells were exposed at any stage of development. Two or 3 weeks after dosing, the animals were mated with females. Body weights were significantly reduced in mice dosed at 1% chemical, but there were no adverse effects on fertility (impairment of epididymal

spermatozoa). A NOAEL of 1,000 mg/kg bw/day was established for male fertility (NICNAS 2013; OECD 2007).

Repeat dose oral 13 weeks studies with C12–15 AS Na (CAS 68890-70-0), C10–16 AS Na (CAS No. 68585-47-7) and C16–18 AS Na (CAS 68955-20-4) gave no indication of adverse effects on reproductive organs (see **Repeat Dose Toxicity – Oral**). At very high doses (around or above 1,000 mg/kg bw/day) increases in relative (but not absolute) testes weights were noted; this effect was not considered as adverse but was attributed to a decrease in body fat or body weight. There were also no adverse histopathological findings at necropsy (REACH n.d.-a; REACH n.d.-b).

Developmental toxicity

These chemicals are not expected to have adverse effects on development, based on the available developmental toxicity studies conducted with various alkyl sulfates (C12 AS Na in mice, rats and rabbits; C12–14 AS Na, C12–15 AS, C13–15 AS Na, C15–16 AS Na, C16–18 AS Na in rats).

In a non-GLP developmental toxicity study conducted similarly to OECD TG 414, female Wistar rats (20 animals/dose) were administered C12–14 AS Na (CAS No. 85585-07-8) by gavage at 63, 125, 250 or 500 mg/kg bw/day from gestation day (GD) 6 until GD 15. At 500 mg/kg bw/day, dams had severe diarrhoea, reduced food intake and reduced body weight (maternal toxicity). There was one death, and 2 animals were euthanised prior to full term. The survivors showed increased number of intrauterine deaths and a reduction in live foetal body weights. There were no gross external or visceral anomalies which could be attributed to treatment. No maternal toxicity effects were seen in the other treatment groups and no developmental toxicity was observed in these groups (REACH n.d.-d).

In a non-GLP and non-guideline developmental toxicity study, female Wistar rats (15 animals/dose) were administered C16–18 AS Na (CAS No. 68955-20-4) by gavage at 112, 225, 450 or 675 mg/kg bw/day from GD 6 until GD 15. Maternal toxicity (diarrhoea and reduced weight gain) was observed at 450 mg/kg bw/day and above. Slight, but significantly reduced body weight was observed in male foetuses in the 450 mg/kg bw/day group. Incidence of macroscopically observed haemorrhage under the capsule of the kidney of 3–5% of foetuses in the 3 lower dose groups. NOAELs of 225 mg/kg bw/day for maternal toxicity and 675 mg/kg bw/day for embryotoxicity were established in this study (REACH n.d.-a).

In developmental toxicity studies in rats (CD), mice (CD-1) and NZW rabbits, the structurally related chemical C12 AS Na (CAS No. 151-21-3) was administered by oral gavage at doses of 0, 0.2, 2, 300 or 600 mg/kg bw/day. Effects on litter parameters were restricted to doses that caused significant maternal toxicity (NICNAS 2013; OECD 2007)

In further developmental and teratogenicity toxicity studies, various alkyl sulfates were administered to rats via oral gavage at up to 1,000 mg/kg bw/day. Adverse developmental effects including embryo death or deformities and litter loss were reported at maternally toxic doses. No decreases in litter size, malformations or significant skeletal defects were observed compared to controls in rats at up to 1,000 mg/kg bw/day (HERA 2002; OECD 2007).

Environmental exposure

These chemicals are used as surfactants in products that are typically released to wastewater as part of their household or commercial use. Depending on the degradation and partitioning processes of chemicals in STPs, a fraction of the quantity of chemicals in wastewater entering STPs will be emitted to rivers or oceans in treated effluent, or to soil by application of biosolids to agricultural land. Emissions of the substances to environmental surface waters, sediment, and soil are considered as part of this evaluation.

A subset of uses may result in direct release to the environment, such as use in car washing products and in fire-fighting foams. In these uses, the chemicals may be emitted directly to the soil compartment, or to surface waters without STP treatment through stormwater drainage systems. However, these are expected to be a minor contribution compared to the widespread, continuous use of personal care and laundry and cleaning products that make up most of the use volume.

Environmental fate

Chemicals in this group are expected to dissociate to an alkyl sulfate anion under environmental conditions in water, sediment and moist soil. The nature of the counterion is not expected to influence the environmental hazard and fate properties of these chemicals.

Dissolution, speciation and partitioning

These chemicals have pKa values around 0.91–1.73 (REACH n.d.-b; REACH n.d.-c; REACH n.d.-d; REACH n.d.-j) and are expected to dissociate into their respective sulfate anions under environmental conditions. As ionic species, these chemicals are not expected to volatilise from water or moist soil.

Chemicals in this group will partition to organic carbon in sludge and sediments. Adsorption increases with increasing alkyl chain length (Cowan-Ellsberry et al. 2014; Fernández-Ramos Carolina et al. 2014), and experimental sediment-water partitioning coefficients (Koc) range from 75 for C8 AS Na (low sorption potential) to 1567 for C14 AS Na (strong–very strong sorption potential) at 25°C and pH 7.6 (OECD 2007).

In aquatic environments, these chemicals are expected to partition significantly to sediments. Releases to wastewater streams are treated at STPs, where they will partition preferentially to the sludge and solids fractions, releasing a relatively minor proportion in effluent. Release to the soil compartment will likely occur through application of STP biosolids residues to land.

Degradation

These chemicals are expected to rapidly and ultimately biodegrade under aerobic and anaerobic conditions in waters, sludge and soils.

Primary biodegradation begins with cleavage of the sulfate group catalysed by alkylsulfatases, which gives the corresponding alkyl (fatty) alcohol and an inorganic sulfate salt (Madsen et al. 2001). This results in loss of surfactant properties (Fendinger et al. 1994). Oxidation of the alcohol by dehydrogenases to a carboxylic (fatty) acid is followed by degradation via β-oxidation and subsequent mineralisation or incorporation into biomass (Könnecker et al. 2011; Madsen et al. 2001). Primary biodegradation is generally complete after a few days, followed by rapid ultimate biodegradation. Slight branching of the alkyl chain does not inhibit degradation (AISE and Cefic 2002; REACH n.d.-k; REACH n.d.-l;

REACH n.d.-m), and variations in the counterion may not have an effect (OECD 2007). However, extremely high concentrations of surfactant may inhibit or damage bacterial cells, preventing them from initiating biodegradation (Zhang et al. 1999).

All of the substances in this group are readily biodegradable (OECD 2007). In tests conducted according to OECD TG 301 B, 301 D and 301 E, the pass levels for ready degradability were reached. For sodium salts of sulfates with alkyl chain lengths between C8 and C18, 69–100% degradation was observed during 28–30 day studies, (OECD 2007; REACH n.d.-a). For UVCBs with alkyl chain lengths between C8 and C18 and various metal and amine counterions, degradation of 77–100% was observed over 28–30 days (OECD 2007; REACH n.d.-e; REACH n.d.-n; REACH n.d.-o; REACH n.d.-p; REACH n.d.-q).

Sewage treatment simulation tests according to OECD TG 303 A (Continuous Activated Sludge tests) led to 97% DOC removal of C12-14 AS Na over 27 days (REACH n.d.-j) and 96% DOC removal of C16 18 AS Na over 30 days (REACH n.d.-h).

Alkyl sulfates are also rapidly biodegradable under anaerobic conditions (OECD 2007). C14 AS Na underwent 80% mineralisation after 17 days (Nuck and Federle 1996) and C18 AS underwent 94% mineralisation after 28 days (AISE and Cefic 2002).

Two studies determined the half-life of C12 AS in surface water to be approximately 0.3–3 days (Anderson et al. 1990; AISE and Cefi 2002), whereas half-lives of 0.26–19.2 days were reported for sea water (George 2002; Jackson et al. 2016).

Tests indicate that alkyl sulfates are completely biodegraded in forest soil, and sulfatase has been isolated from soil bacteria (Fendinger et al. 1994). A sediment biodegradation test carried out in the US found that C12 AS underwent rapid primary degradation, with less than 2% of the substance remaining within the first day of the experiment. The total measured mineralisation was 78% after 149 days in one creek, and 52% after 92 days in the other (McDonough et al. 2016).

Abiotic degradation of alkyl sulfates is not expected to be significant. Photodegradation is not relevant due to the low volatility and the lack of a chromophore in the substances in this group (Fendinger et al. 1994; Könnecker et al. 2011). The compounds hydrolyse in hot alkaline and acidic media, but are stable under environmentally relevant conditions (OECD 2007).

Bioaccumulation

These chemicals are not expected to bioaccumulate. Non-standard tests in fish indicate a low bioaccumulation potential based on bioconcentration factor (BCF) values below domestic categorisation thresholds (≤2,000 L/kg) for bioaccumulation hazards (EPHC 2009).

One bioaccumulation study using C14-15 AS measured BCFs of 180–422 for Fathead minnow (*Pimephales promelas*), 402–972 for Channel catfish (*Ictalurus punctatus*) and 81–400 for Asiatic clam (*Corbicula fluminea*) (Könnecker et al. 2011).

In another study, carp (*Cyprinus carpio*) were exposed to 0.25 and 0.5 mg/L solutions of ^{35}S-labelled versions of C12 AS Na, C14 AS Na, and C16 AS Na. Exposure occurred for 72 hours, followed by a depuration period in freshwater of 120 hours. Maximum uptake was observed after 24 hours. Whole body BCF values of 2.1–73 L/kg wet weight (wwt) were determined, with larger BCFs attributed to alkyl sulfates with longer alkyl chains (Wakabayashi et al. 1978; Wakabayashi et al. 1980). Additionally, elevated concentrations of radioactivity were seen in the gall bladder and hepatopancreas, both vital organs in the

absorption and metabolism of lipids, which may indicate recognition of dodecyl sulfate as a lipid-like food source (Wakabayashi et al. 1978).

Despite use as potential lipid food source, depuration of alkyl sulfates appears to be rapid. In carp, the concentrations of the C12 AS, C14 AS and C16 AS were similar with approximately 40–50% of radioactivity found within the fish after 120 hours of depuration (Wakabayashi et al. 1978; Wakabayashi et al. 1980). In goldfish (*Carassius auratus*), the whole body radioactivity of C12 species reduced by 38% in unfed fish and 68% in fed fish after 24 hours, which indicates that feeding causes an increase in the excretion rate (Tovell et al. 1975). In goldfish, butyric acid-4-sulfate was identified as a major metabolite of C12 AS, suggesting that metabolism of C12 AS did not occur through the cleaving of the sulfate head (Tovell et al. 1975).

Measured BCF values for the mussel *Mytilus galloprovincialis* using C12 AS were found to be <1 L/kg (Freitas et al. 2021).

Environmental transport

These chemicals are not expected to undergo long-range transport due to the short degradation half-lives observed under environmental and screening test conditions.

Predicted environmental concentration (PEC)

The PECs for the chemicals in this group have been selected based on international monitoring of these chemicals in surface water and sediments. The PECs for the key environmental compartments are 7.4 µg/L in STP effluent, 176 ng/L in fresh surface water, and 17.6 ng/L in seawater.

Concentrations of alkyl sulfates in wastewater treatment plants (WWTPs) have been measured in the Netherlands and the US (Cowan-Ellsberry et al. 2014; Fendinger et al. 1992; Fernández-Ramos et al. 2012; Matthijs et al. 1999; McAvoy et al. 1998; Popenoe et al. 1994; Sanderson et al. 2006). Average measured alkyl sulfate concentrations in WWTP influents were in the range of 0.082–0.578 mg/L. Effluent concentrations vary according to the treatment process used. Effluents from activated sludge WWTPs typically contain lower levels of alkyl sulfates than effluents from trickling filter WWTPs. Effluents from trickling filter WWTPs contained average alkyl sulfate concentrations of 0.014–0.041 mg/L (Cowan-Ellsberry et al. 2014; McAvoy et al. 1998). Effluents from activated sludge WWTPs contained average alkyl sulfate concentrations of 0.001–0.0074 mg/L, with maximum values in the range of 0.0026–0.0158 mg/L (Fernández-Ramos et al. 2012; Matthijs et al. 1999; Sanderson et al. 2006).

In Australia, 80% of wastewater is subject to at least secondary treatment (BOM 2023). An internal survey of Australian WWTPs indicated that only a minor proportion of wastewater is treated using trickling-filter processes and that most Australian secondary treatment plants currently utilise activated sludge processes. The reasonable worst case concentration for alkyl sulfates in STP effluents is therefore predicted to be 7.4 µg/L, based on the highest average reported alkyl sulfate concentration in effluent after activated sludge treatment in international monitoring studies.

In river water, measured concentrations of C12–-C15 alkyl sulfate were 1.5–176 ng/L upstream and 10–112 ng/L downstream from WWTPs that receive low input (0–20%) from industrial sources (Popenoe et al. 1994; Sanderson et al. 2006). C12 alkyl sulfate averages of 100 ng/L in rivers and 80 ng/L in lakes were measured in a Swedish survey of 24 river and 13 lake sites (Malnes et al. 2022), whereas C12 AS was only seen in one river sample in

Turkey at 20 µg/L (Emadian et al. 2021). Values up to 8.5 mg/L C12 AS were seen in Brazilian rivers, with higher levels occurring near industrial areas (Freitas E and Rocha 2012). 176 ng/L has been used as a reasonable worst-case freshwater value as this represents the highest measured concentration in freshwater in areas that are unlikely affected by direct industrial releases. 17.6 ng/L has been used as an estimate for concentrations in seawater, based on the freshwater value and a dilution factor of 10.

Environmental effects

These chemicals have the potential to cause toxic effects in aquatic organisms across multiple trophic levels. The aquatic toxicity of alkyl sulfates is well studied, and acute and chronic endpoints are available for many species across multiple trophic levels. Available endpoints are suitable for read across to less data rich chemicals in the group, because they dissociate to the common alkyl sulfate anion.

Data are available for both freshwater and marine species. A comparison of the two environments reveals that marine data generally fall within freshwater data ranges, which suggests that marine species are equally sensitive towards alkyl sulfate surfactants as freshwater species (Jackson et al. 2016).

Some tested chemicals are alkyl sulfates containing various chain lengths. Weighted average chain lengths have been calculated where composition information is available.

Some of the tested materials are of low purity. Whereas these substances may contain significant amounts of unknown compounds, endpoints have normally been measured based on active (alkyl sulfate) ingredients.

Toxicity varies with alkyl chain length. C8 to C12 alkyl sulfates have low to moderate toxicity while C14 and C16 alkyl sulfates are highly toxic (OECD 2007). Toxicity then decreases with increasing chain length for alkyl sulfates longer than C16. This pattern does not appear to change with different fish species. Toxicity testing becomes more difficult at concentrations above CMC values due to proportions of the test substance being present as micelles. The bioavailability of the test substance may vary due to solubility limitations, particularly for longer chain homologs (Könnecker et al. 2011).

The aquatic toxicity of surfactant chemicals is generally explained by their interaction with cell membranes (Könnecker et al. 2011). Studies have shown that the temperature, water hardness and salinity (for marine or brackish species) have differing effects on toxicity depending on the aquatic species (Freitas et al. 2021; Persoone et al. 1989). Toxicity on aquatic organisms is mainly determined by the anion and not affected by counterions (Könnecker et al. 2011).

Effects on aquatic life

Freshwater acute toxicity

The following measured median effective concentration (EC50) and median lethal concentration (LC50) values for alkyl sulfates in model organisms were retrieved from the OECD SIDS dossier for alkyl sulfates, alkane sulfonates and α-olefin sulfonates (OECD 2007), the registration dossier for individual chemicals under REACH legislation (REACH n.d.-a; REACH n.d.-b; REACH n.d.-d; REACH n.d.-e; REACH n.d.-f; REACH n.d.-h; REACH n.d.-n; REACH n.d.-o; REACH n.d.-q), and the scientific literature (Annunziato et al. 2020; Dyer et al. 1997; Kikuchi and Wakabayashi 1984):

Fish

Alkyl chain length	Endpoint	Method
C8	96 h LC50 > 100 mg/L	*Danio rerio* (zebrafish) semi-static nominal concentration OECD TG 203
C10	96 h LC50 = 177 mg/L	*Danio rerio (zebrafish)* semi-static nominal concentration ISO 7346-1
C8–14 (C11.7 average)	96 h LC50 = 5.3 mg/L	*Danio rerio (zebrafish)* semi-static nominal concentration ISO 7346-1
C12	96 h LC50 = 3.67 mg/L	*Danio rerio* (zebrafish) embryo semi-static nominal concentration OECD TG 236
C14	96 h LC50 = 0.66 mg/L	*Danio rerio* (zebrafish) embryo semi-static nominal concentration OECD TG 236
C12–18 (C14.4 average)	96 h LC50 = 1.3 mg/L	*Danio rerio* (zebrafish) flow-through nominal concentration OECD TG 203
C16	48 h LC50 = 0.61 mg/L	*Oryzias latipes* (medaka) semi-static nominal concentration Japanese industrial standard (JIS) K0102-1981
C16–18 (C17.2 average)	96 h LC50 = 5.2 mg/L	*Danio rerio* (zebrafish) semi-static nominal concentration OECD TG 203

Invertebrates

Alkyl chain length	Endpoint	Method
C8	48 h EC50 (immobilisation) > 100 mg/L	*Daphnia magna* (water flea) semi-static nominal concentration OECD TG 202
C12	48 h LC50 = 5.55 mg/L	*Ceriodaphnia dubia* (water flea) flow-through measured concentration OECD TG 202 equivalent
C14	48 h LC50 = 1.58 mg/L	*Ceriodaphnia dubia* (water flea) flow-through measured concentration OECD TG 202 equivalent
C12–18 (C14.4 average)	48 h EC50 (immobilisation) = 2.8 mg/L	*Daphnia magna* (water flea) static nominal concentration OECD TG 202
C14–15 (C14.6 average)	48 h LC50 = 0.80 mg/L	*Ceriodaphnia dubia* (water flea) flow-through measured concentration OECD TG 202

Algae

Alkyl chain length	Endpoint	Method
C10	72 h EC50 (growth) = 8.64 mg/L	*Raphidocelis subcapitata* (green algae) static nominal concentration OECD TG 201
C12	72 h EC50 (biomass) = 53 mg/L	*Desmodesmus subspicatus* (green algae) Static nominal concentration DIN 38412, part 9
C12–14 (C12.5 average)	72 h EC50 (growth) = 27 mg/L	*Raphidocelis subcapitata* (green algae) static nominal concentration OECD TG 201
C12–18 (C13.6 average)	96 h EC50 (cell number) = 38 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration DIN 38412, part 9
C14–15	70 h EC50 (growth) = 4.9 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration OECD TG 201

Alkyl chain length	Endpoint	Method
C16–18 (C17.2 average)	72 h EC50 (biomass) = 30 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration DIN 38412 part 9

A study investigating the effect of C12 alkyl sulfate on the freshwater planarian *Dugesia japonica* observed a 48 h LC50 of 1.05 mg/L (Li 2012).

Freshwater chronic toxicity

The following measured EC50, no observed effect concentration (NOEC) and 10% effective concentration (EC10) values for alkyl sulfates in model organisms were retrieved from the OECD SIDS dossier for alkyl sulfates, alkane sulfonates and α-olefin sulfonates (OECD 2007), the registration dossier for individual chemicals under REACH legislation (REACH n.d.-b; REACH n.d.-f; REACH n.d.-h; REACH n.d.-j; REACH n.d.-n; REACH n.d.-o), and the scientific literature (Freitas and Rocha 2012):

Fish

Alkyl chain length	Endpoint	Method
C12	28 d LC10 = 3.6 mg/L	*Pimephales promelas* (fathead minnow larvae) flow-through measured concentration OECD TG 210
C14–15	34 d NOEC (mortality) = 0.11 mg/L	*Pimephales promelas* (fathead minnow larvae) flow-through measured concentration OECD TG 210 (equivalent)
C16–18 (C17.2 average)	14 d NOEC (mortality) = 1.65 mg/L	*Danio rerio* (zebrafish) semi-static nominal concentration OECD TG 204

Application of the fish embryo acute toxicity test OECD TG 236 to Aphanius dispar (Arabian killifish) embryos exposed to C12 alkyl sulfates for 5–12 days found delayed hatching at or below 6 mg/L (Saeed et al., 2015).

Invertebrates

Alkyl chain length	Endpoint	Method
C10	21 d NOEC (reproduction) = 1.4 mg/L	*Daphnia magna* (water flea) semi-static measured concentration OECD TG 211
C12	21 d NOEC (reproduction) = 1 mg/L	*Pseudosida ramosa* (water flea) semi-static nominal concentration OECD TG 211
C12–14 (C12.9 average)	21 d EC50 (reproduction) = 5.7 mg/L	*Daphnia magna* (water flea) semi-static OECD TG 211
C16–18 (C16.8 average)	21 d EC50 (reproduction) = 4.2 mg/L	*Daphnia magna* (water flea) semi-static OECD TG 211

Reproduction assessments were carried out with *Pseudosida ramosa* (water flea). Chronic exposure (21 d) to C12 alkyl sulfates led to NOEC and LOEC values of 1 mg/L and 2 mg/L, respectively, for fecundity and fertility (Freitas and Rocha 2012).

Algae

Alkyl chain length	Endpoint	Method
C12	72 h NOEC (biomass) = 30 mg/L	*Desmodesmus subspicatus* (green algae) Static nominal concentration DIN 38412, part 9
C12–18 (C13.6 average)	96 h EC10 (cell number) = 7.4 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration DIN 38412, part 9
C14–15	70 h EC10 (growth) = 1.64 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration OECD TG 201
C16–18 (C17.2 average)	72 h EC10 (biomass) = ca. 19 mg/L	*Desmodesmus subspicatus* (green algae) static nominal concentration DIN 38412 part 9

Marine acute toxicity

Acute toxicity information for marine organisms is only available for C12 alkyl sulfates.

The following measured EC50 and LC50 values for alkyl sulfates in model organisms were retrieved from the OECD SIDS dossier for alkyl sulfates, alkane sulfonates and α-olefin

sulfonates (OECD 2007), the registration dossier for individual chemicals under REACH legislation (REACH n.d.-b), and the scientific literature (Nunes et al. 2005):

Taxon	Endpoint	Method
Fish	96 h LC50 = 2.8 mg/L	*Menidia menidia* (American silverside) static nominal concentration ASTM E-35
Invertebrate	48 h LC50 = 3.15 mg/L	*Artemia salina* (brine shrimp) static nominal concentration
Algae	96 h EC50 (growth) = 30.2 mg/L	*Tetraselmis chuii* (green microalgae) static nominal concentration OECD TG 201

A study measuring the effect of C12 alkyl sulfate on larvae of the European spider crab (*Maja squinado*) observed a 48 h LC50 of 0.687 mg/L (Bellas et al. 2005). A study investigating the toxicity of C12 alkyl sulfate on mollusc embryos observed an 48h IC50 of 0.84 mg/L (Jorge and Moreira 2005).

Marine chronic toxicity

Chronic toxicity information for marine organisms is only available for C12 alkyl sulfates.

The following measured LC50 and NOEC values for C12 alkyl sulfates in model organisms were retrieved from the scientific literature (Han and Choi 2005; Saeed et al. 2015):

Taxon	Endpoint	Method
Fish	10 d LC50 = 9.37 mg/L	*Aphanius dispar* (Arabian killifish) static nominal concentration OECD TG 236
Algae	5 d NOEC (reproduction) = 1.5 mg/L	*Ulva pertusa* (green algae) static

Effects on terrestrial life

Exposure of wheat (*Triticum aestivum*) seedlings to C12 alkyl sulfate caused decreased germination rate, and reduced root length and biomass at concentrations greater than 100 mg/L. A 50% root length inhibition concentration (IC50) value of 270 mg/L was calculated (Chang et al. 2015).

Effects on sediment dwelling life

The lugworm *Arenicola marina* was exposed to C12 alkyl sulfate for 48 h in a semi-static test, to give an LC50 of 15.2 mg/L at nominal concentrations (Conti 1987).

Endocrine effects

No endocrine effects have been identified for chemicals in this group.

Predicted no-effect concentration (PNEC)

A PNEC for alkyl sulfates in freshwater of 11 µg/L was derived from the measured chronic ecotoxicity fish endpoint for C14-15 AS (34 d NOEC = 110 µg/L) using an assessment factor of 10. This assessment factor was selected, as reliable chronic ecotoxicity data are available for alkyl sulfates with similar chain lengths over three trophic levels.

A PNEC for alkyl sulfates in seawater was calculated to be of 2.8 µg/L. Only two chronic toxicity endpoints were available for marine organisms, and so two different PNECs were calculated. One PNEC was derived from the acute endpoints and one from the chronic endpoints. The two PNECs were compared, and the most conservative value was taken. A PNEC of 2.8 µg/L was derived from the measured acute fish ecotoxicity endpoint (96 h LC50 = 2.8 mg/L) and an assessment factor of 1,000. A PNEC of 15 µg/L was derived from the measured algae chronic ecotoxicity endpoint (5 d NOEC = 1.5 mg/L) and an assessment factor of 100.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to domestic environmental hazard thresholds (DCCEEW 2022) is presented below:

Persistence

Not persistent (Not P). Based on measured degradation studies, the chemicals in the group are categorised as not persistent.

Bioaccumulation

Not bioaccumulative (Not B). Based on low measured bioconcentration factors (BCF) in fish, the chemicals in the group are categorised as not bioaccumulative.

Toxicity

Toxic (T). Based on available acute ecotoxicity values below 1 mg/L, the C14 alkyl sulfate chemicals (CAS No. 1191-50-0; 4492-78-8; 25446-91-7) and the C16 alkyl sulfate chemicals (CAS No. 143-02-2; 1120-01-0; 4696-47-3; 51541-51-6) are categorised as Toxic.

Not Toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and evidence of low chronic toxicity, all other chemicals are categorised as not toxic.

Environmental hazard classification

The chemicals have been classified according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for environmental hazards. The chemicals in this evaluation which are UVCBs have been classified according to the criteria for mixtures, based on the “summation method” and the expected alkyl chain length distribution (UNECE 2017).

The following chemicals are not classified for aquatic hazards:

- C6 alkyl sulfates (CAS No. 2207-98-9)

- C8 alkyl sulfates (CAS No. 142-31-4; 30862-34-1)
- C9 alkyl sulfates (CAS No. 26856-96-2).

The remaining chemicals satisfy the criteria as follows:

Hazardous to the aquatic environment (acute / short-term)

Based on measured EC50 and LC50 the range 1–10 mg/L, the following chemicals satisfy the criteria for hazard category 'Aquatic Acute 2' with the hazard statement 'H401: Toxic to aquatic life':

- C10 alkyl sulfates (CAS No. 142-87-0; 13177-52-1; 68299-17-2; 39943-70-9)
- C12 alkyl sulfates (CAS No. 151-41-7; 139-96-8; 143-00-0; 4722-98-9; 21142-28-9; 65104-49-6; 66161-60-2)
- C13 alkyl sulfates (CAS No. 3026-63-9)
- C18 alkyl sulfates (CAS No. 143-03-3; 1120-04-3; 4696-46-2)
- C20 alkyl sulfates (CAS No. 13177-49-6).

The following UVCB substances are expected to contain at least 25% of alkyl sulfates with C10, C12, and/or C13 chain lengths (but <25 % alkyl sulfates with C14 and/or C16 chain lengths). Therefore, these UVCB substances also satisfy the criteria for hazard category 'Aquatic Acute 2' with the hazard statement 'H401: Toxic to aquatic life':

- C6–10 alkyl sulfates (CAS No. 68187-17-7)
- C6–12 alkyl sulfates (CAS No. 90583-25-8)
- C9–11 alkyl sulfates (CAS No. 84501-49-5)
- C9–13 alkyl sulfates (CAS No. 72906-11-7).

Based on measured or estimated EC50 and LC50 <1 mg/L, the following chemicals satisfy the criteria for hazard category 'Aquatic Acute 1' with the hazard statement 'H400: Very toxic to aquatic life':

- C14 alkyl sulfates (CAS No. 1191-50-0; 4492-78-8; 25446-91-7)
- C16 alkyl sulfates (CAS No. 143-02-2; 1120-01-0; 4696-47-3; 51541-51-6).

The following UVCB substances are expected to contain at least 25% of alkyl sulfates with C14 and/or C16 chain lengths. Therefore, these UVCB substances also satisfy the criteria for hazard category 'Aquatic Acute 1' with the hazard statement 'H400: Very toxic to aquatic life':

- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0)
- C12–14 alkyl sulfates (CAS No. 85586-07-8; 85681-66-9; 90583-16-7; 90583-18-9; 90583-23-6)
- C12–15 alkyl sulfates (CAS No. 68815-25-8; 68890-70-0)
- C12–16 alkyl sulfates (CAS No. 73296-89-6; 85252-21-7)
- C12–18 alkyl sulfates (CAS No. 68955-19-1, 90583-13-4)
- C16–18 alkyl sulfates (CAS No. 68955-20-4)
- Coco alkyl sulfates (CAS No. 97375-27-4).

Hazardous to the aquatic environment (long-term)

All chemicals in this evaluation are rapidly degradable. Based on measured NOEC and EC10 endpoints in the range 0.1–1 mg/L inclusive, the following chemicals satisfy the criteria for hazard category 'Aquatic Chronic 3' with the hazard statement 'H412: Harmful to aquatic life with long lasting effects':

- C12 alkyl sulfates (CAS No. 151-41-7; 139-96-8; 143-00-0; 4722-98-9; 21142-28-9; 65104-49-6; 66161-60-2)
- C13 alkyl sulfates (CAS No. 3026-63-9)
- C14 alkyl sulfates (CAS No. 1191-50-0; 4492-78-8; 25446-91-7).

The following UVCB substances are expected to contain at least 25% of alkyl sulfates with C12, C13, and/or C14 chain lengths. Therefore, these UVCB substances also satisfy the criteria for hazard category 'Aquatic Chronic 3' with the hazard statement 'H412: Harmful to aquatic life with long lasting effects':

- C8–14 alkyl sulfates (CAS No. 85665-45-8; 90583-10-1)
- C8–18 alkyl sulfates (CAS No. 68130-43-8; 85586-38-5; 90583-22-5)
- C9–13 alkyl sulfates (CAS No. 72906-11-7)
- C10–16 alkyl sulfates (CAS No. 68081-96-9; 68081-97-0; 68585-44-4; 68585-47-7; 68908-44-1; 68910-01-0)
- C12–14 alkyl sulfates (CAS No. 85586-07-8; 85681-66-9; 90583-16-7; 90583-18-9; 90583-23-6)
- C12–15 alkyl sulfates (CAS No. 68815-25-8; 68890-70-0)
- C12–16 alkyl sulfates (CAS No. 73296-89-6; 85252-21-7)
- C12–18 alkyl sulfates (CAS No. 68955-19-1, 90583-13-4)
- Coco alkyl sulfates (CAS No. 97375-27-4).

All other chemicals in this evaluation are not classified for long-term aquatic hazards.

Environmental risk characterisation

Based on the PEC and PNEC values determined above, the following Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the chemicals in this group into STPs, freshwater and marine water:

Compartment	PEC	PNEC	RQ
STP effluent	7.4 µg/L	11 µg/L	0.67
Surface water (fresh)	0.176 µg/L	11 µg/L	0.016
Surface water (marine)	0.0176 µg/L	2.8 µg/L	<0.01

Given that the calculated RQ values are less than 1, these chemicals are not expected to pose a significant risk to the aquatic environment, as environmental concentrations are below levels likely to cause harmful effects in typical environmental conditions.

The ongoing flow of alkyl sulfates into the environment (through effluents and runoff) may continuously replace degraded chemicals, resulting in chronic exposures despite rapid

degradation (Sanderson et al. 2006). However, adequate chronic toxicity information was available to assess the risk of these exposures.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in scope. Some relatively common data limitations can be addressed through use of conservative assumptions (OECD 2019) or quantitative adjustments such as assessment factors (OECD 1995). Others must be addressed qualitatively, or on a case-by-case basis (OECD 2019).

The most consequential areas of uncertainty for this evaluation are:

- Limited Australian monitoring information was available for the chemicals in this evaluation.
- Insufficient information is available to characterise the terrestrial and sediment toxicity of the chemicals in this evaluation.

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