Australian Government
Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

Dodecanoic acid, 2-sulfoethyl ester, sodium salt (1:1)

Assessment statement (CA10078)

11 December 2025

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AICIS assessment (CA10078)

Chemical in this assessment

Name	CAS registry number
Dodecanoic acid, 2-sulfoethyl ester, sodium salt (1:1)	7381-01-3

Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act 2019* (the Act).

Certificate application type

AICIS received the application in a Health and Environment Focus type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 195 tonnes/year
- as imported in neat form for local reformulation
- as imported or reformulated into finished end use products for end use in personal care products (cosmetics) except oral care products
- as imported or reformulated into finished end use products at less than 10% concentration

Summary of assessment

Summary of introduction, use and end use

The assessed chemical will not be manufactured in Australia. It will be imported in neat form for local reformulation or as a component of finished end use products. The assessed chemical has end use in personal care products (cosmetics) except oral care products. The imported or reformulated end use products will contain the assessed chemical at less than 10% concentration and are proposed to be used by professional workers and members of the public.

Human health

Summary of health hazards

The submitted toxicological data on the assessed chemical and analogues (see **Supporting information**) indicate that the assessed chemical is:

- of low acute oral toxicity
- likely to cause irritation effects to the skin and eyes (see below)

- unlikely to be a skin sensitiser
- unlikely to cause adverse effects following repeated oral or dermal exposure (see below)
- not genotoxic

A skin irritation study and an eye irritation study provided on an analogue chemical indicated skin irritation (slight) and eye irritation. Some formulations containing the same analogue were reported to have slight to moderate irritation to the skin, and to be non-irritating to severely irritating to eyes (Burnett et al. 2017). However, another structurally similar isethionate (ethanesulfonic acid, 2-hydroxy-, sodium salt; CAS No. 1562-00-1) was reported as non-irritating to the skin and eyes (Burnett et al. 2017). Based on the available read-across data, the potential for the assessed chemical to cause irritation effects to the skin and eyes cannot be ruled out.

Two repeated dose toxicity studies, one reproduction/developmental toxicity screening study and one developmental toxicity study conducted in rats were provided for two analogues. In the 28-day dermal toxicity study, Analogue 1 showed no adverse systemic toxicity effects up to the highest dose tested (NOAEL = 2,070 mg/kg bw/day). In the 28-day dietary study, the NOAEL of Analogue 1 was above 600 mg/kg bw/day (the highest dose tested). Analogue 2 showed no reproductive/developmental effects or systemic toxicity effects in the two reproduction/ developmental studies at up to 1,000 mg/kg bw/day (the highest dose tested).

No inhalation toxicity data were provided for the assessed chemical.

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed chemical satisfies the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for worker health and safety as adopted for industrial chemicals in Australia.

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

Summary of health risk

Public

There will be widespread and repeated exposure of the public to the assessed chemical at less than 10% concentration when using a wide range of cosmetic products containing the assessed chemical. The principal route of exposure will be dermal, while incidental oral or ocular exposure is also possible. Inhalation exposure is not expected given the low vapour pressure of the assessed chemical and the proposed non-spray use of cosmetic products containing the assessed chemical.

The assessed chemical is likely to have irritation effects to the skin and eyes. However, skin and eye irritation effects are not expected to occur from use of the assessed chemical at the proposed end use concentrations (less than 10%) in cosmetics.

A dermal absorption (DA) study was conducted on the assessed chemical, and the DA rate was calculated to be 1.1%. Using the 1.1% DA rate, consumers simultaneously using multiple

cosmetic and domestic products may be systemically exposed to the assessed chemical at approximately 256 µg/kg bw/day through repeated or prolonged dermal exposure (see **Supporting information** section). As the DA rate of the chemical could vary with other ingredients in cosmetic formulations and the assessed chemical is a small molecule (MW = 331.43 g/mol), this low systemic exposure estimation may not be the worst case. Considering the low systemic toxicity of the assessed chemical, health risks from repeated exposure to the public are not expected. This is supported by the Cosmetic Ingredient Review (CIR) Expert Panel's conclusion that the 12 evaluated isethionate salts are safe in the present practices of use and concentration in cosmetics, when formulated to be non irritating (Burnett et al. 2017). The evaluated isethionate salts included the assessed chemical, and the proposed end use and end use concentrations of the assessed chemical are within the range reported in the CIR report.

This assessment does not identify any risks to public health that require specific risk management measures.

Workers

Reformulation workers may be incidentally exposed to the assessed chemical at up to 100% concentration during reformulation processes mainly via the dermal route, while ocular and inhalation exposures are also possible. To mitigate potential skin and eye irritation and inhalation risks to reformulation workers, control measures would be required (see **Means for managing risk**) to minimise the exposure. It is anticipated by the applicant that engineering controls such as enclosed automated processes and local ventilation will be implemented where possible, and use of appropriate personal protective equipment (PPE) such as safety glasses, impervious chemical resistant gloves, protective clothing and respiratory protection will reduce worker exposure.

Professional workers using end use products in cosmetic businesses may experience exposure via dermal and accidental ocular exposure to the assessed chemical at less than 10% concentration. Due to the low vapour pressure of the assessed chemical and the proposed non-spray use of cosmetics containing the assessed chemical, inhalation exposure is not expected. The professional workers may wear some PPE (including gloves, coveralls and face masks or safety glasses). If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the same end use products containing the assessed chemical. Therefore, no additional risk management measures are required for these workers.

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022) and based on the available data the assessed chemical is:

- Not Persistent (not P)
- Not Bioaccumulative (not B)
- Not Toxic (not T)

Environmental hazard classification

The assessed chemical satisfies the criteria for classification according to the GHS for environmental hazards (UNECE, 2017) as follows. Considerations were also made for the degradation of the assessed chemical.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 3	H402: Harmful to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 3	H412: Harmful to aquatic life with long lasting effects

Summary of environmental risk

The assessed chemical is a component in personal care products (cosmetics). Use of these products is expected to result in the release of the assessed chemical "down the drain" and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

The assessed chemical does not meet any of the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022). It is unlikely to have unpredictable long-term effects, and its risk may be estimated by the risk quotient method (RQ = PEC ÷ PNEC). Based on calculated RQ values < 1 for the river and ocean compartments, the environmental risk from the introduction of the assessed chemical can be managed.

Means for managing risk

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 (see **Hazard classifications relevant for worker 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.

The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during reformulation:

- Use of engineering controls such as
  - Enclosed and automated systems where possible
  - Adequate workplace ventilation to avoid accumulation of mists or aerosols
- Use of safe work practices to
  - Avoid contact with skin and eyes

    - Avoid inhalation of mists or aerosols

- Use of personal protective equipment (PPE)
    - Impervious gloves
    - Protective clothing
    - Safety glasses
    - Respiratory protection where local ventilation may be inadequate

- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

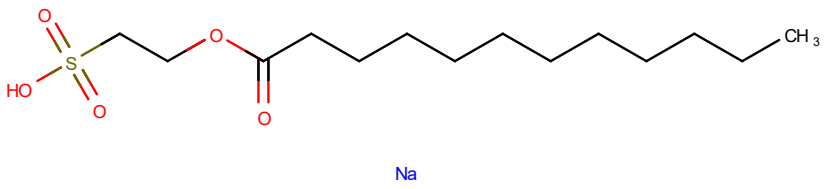
1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	7381-01-3
CAS name	Dodecanoic acid, 2-sulfoethyl ester, sodium salt (1:1)
Molecular formula*	$C_{14}H_{28}O_5S.Na$
Associated names	Sodium 2-sulfoethyl laurate; 2-Sulfoethyl dodecanoate sodium salt
Molecular weight (g/mol)*	331.43
SMILES (canonical)	[Na]O=C(OCCS(=O)(=O)O)CCCCCCCCCCC

Structural formula/Representative structure *



Additional chemical identity information

The substance has a typical purity of ~80%.

* Note: This chemical is a salt and has been represented according to CAS nomenclature and identity conventions.

Relevant physical and chemical properties

Physical form	White solid
Melting point	36 °C
Boiling point	Decomposes at 275 °C prior to boiling
Density	1,210 kg/m^3 at 20 °C
Vapour pressure	< 8.4 × 10^{-10} kPa at 20 °C < 2.2 × 10^{-9} kPa at 25 °C
Water solubility	1.29 g/L at 20 °C
Surface tension	33.5 mN/m at 20 °C
Critical micelle concentration	2.6 g/L

Particle Size	d10: ~445 µm d50: ~977 µm d90: ~1564 µm < 10 µm: 0% < 100 µm: < 0.11%
Ionisable in the environment	yes
pK_a	1.1 for alkyl isethionates and 4.8 for fatty acids (Calculated using ACD/Labs software (v.2022.2.3))
log K_{ow}	-1.56 and 0.3
Log K_{oc}	3.2

Human exposure

Public

Dermal exposure of the public to the assessed chemical at less than 10% concentration will be widespread and frequent across the use of a variety of cosmetic products. Incidental oral and ocular exposure to the chemical at less than 10% concentration may also be possible. Due to the low vapour pressure of the assessed chemical and the proposed non-spray use of cosmetics containing the assessed chemical, inhalation exposure is not expected.

Dermal exposure

Data on typical use patterns of product categories in which the assessed chemical may be used on a daily basis are shown in the following table and these are based on information provided in the literature (SCCS 2012; Cadby et al. 2002; ACI 2010; Loretz et al. 2006). For the purposes of exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. A dermal absorption (DA) study was conducted on the assessed chemical and a DA rate of 1.1% is used for the systemic exposure assessment. An average body weight (BW) of 60 kg is used for male and female adults for calculation purposes.

Cosmetic products

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Body lotion	7,820	10	1	0.143
Face cream	1,540	10	1	0.028
Hand cream	2,160	10	1	0.040
Deodorant (non-spray)	1,500	10	1	0.028
Shampoo	10,460	10	0.01	0.002

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Conditioner	3,920	10	0.01	0.001
Shower gel	18,670	10	0.01	0.003
Hand wash soap	20,000	10	0.01	0.004
Hair styling products	4,000	10	0.1	0.007
Total				**0.256**

C = maximum intended concentration of assessed chemical; RF = retention factor
Daily systemic exposure = (Amount × C × RF × DA)/BW

Overall systemic exposure

Using a 1.1% DA rate, the worst-case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the assessed chemical at the maximum intended concentrations specified in various product types. This would result in a combined internal dose of 0.256 mg/kg bw/day for the assessed chemical. As the DA rate of the chemical could vary with other ingredients in cosmetic formulations and the assessed chemical is a small molecule (MW = 331.43 g/mol), using a 1.1% DA rate to estimate systemic exposure may not be the worst case. However, there were no adverse effects reported in the 28-day repeated dose dermal and oral toxicity studies of the analogue chemicals at up to the highest doses tested, implying that there will be no adverse systemic toxicity effects from the assessed chemical when used repeatedly. The NOAEL of the repeated dose dermal toxicity was 2,070 mg/kg bw/day (the highest dose tested) and the NOAEL of the repeated dose oral (diet) toxicity was 10,000 ppm (above 600 mg/kg bw/day; the highest dose tested). Therefore, a margin of exposure (MoE) for the proposed use in cosmetics has not been calculated.

Health hazard information

Limited toxicological data (a dermal absorption study and one genotoxicity study) were provided for the assessed chemical. Toxicological data of two analogues (UVCB substances (unknown or variable composition, complex reaction products or biological materials)) which consist of the same type of constituents as in the assessed chemical (alkyl isethionates and free fatty acids) were used for read-across for other toxicological endpoints. Analogue 1 is fatty acids, coco, 2-sulfoethyl esters, sodium salts (CAS No. 61789-32-0) and Analogue 2 is fatty acids, $C_{12\text{-}18}$ and C_{18}-unsatd., 2-sulfoethyl esters, sodium salts (CAS No. 85408-62-4).

Dermal absorption

An *in vitro* skin absorption study (OECD TG 428) was conducted on the assessed chemical. In this study, [^{14}C]-labelled assessed chemical was applied topically at 16.7% w/w concentration (in water) to 12 samples of human split-thickness skin membranes. The total absorbed dose, dermal delivery, potentially absorbable dose, and mass balance were determined to be 0.11%, 0.62%, 0.93% and 98.83% of the applied dose, respectively, based on the test substance recovered from the stratum (0.31%), epidermis (0.35%), dermis (0.16%) and receptor fluid (0.11%). The mean relative permeation into the receptor fluid occurring within half of the sampling period (t0.5) was calculated by the applicant, according to the Guidance on Dermal Absorption (EFSA 2017). The calculated t0.5 of 65.35% indicated

incomplete absorption (< 75%). The dermal absorption rate was calculated to be 1.1% according to the EFSA Guidance. However, dermal penetration of the assessed chemical may vary based on the other ingredients in a product formulation. The metabolism potential of the skin tissue was not evaluated. In addition, surfactants such as the assessed chemical can modify cellular membranes and increase absorption of itself and other chemicals in the formulation. The possibility of the assessed chemical breaking down on the skin and resulting in dermal absorption of any metabolites cannot be ruled out, as it was not investigated in the dermal absorption study.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 401), Analogue 1 was administered to Sprague-Dawley rats (n = 5/sex/group) at a single dose of 2,000 mg/kg bw. All animals survived during the 14-day observation period and no signs of systemic toxicity were noted. All animals showed expected body weight gains and no treatment-related gross necropsy findings were observed. The acute oral median lethal dose (LD50) of the test substance was determined to be > 2,000 mg/kg bw.

Corrosion/Irritation

Skin irritation

In a skin irritation study (similar to OECD TG 404), Analogue 1 was applied to 8 New Zealand white rabbits, under semi-occlusive conditions, at 10%, 25%, 40%, 55%, 70% and undiluted concentrations for 4 hours. The treated sites were evaluated for irritation upon the patch removal, followed by 24, 48 and 72 hours. After application of the test substance for 4 hours, all treated sites showed very slight to slight erythema and oedema. At the 24-hour observation, very slight to moderate erythema and very slight to slight oedema were observed in all treated sites. At the 48-hour observation, signs of improvement were observed with some animals showing complete recovery. At the 72-hour observation, more animals had shown complete recovery, although very slight to slight erythema and oedema persisted in some animals. The irritation scores provided in the study were not standardised. Based on the reported skin effects, the test substance is slightly irritating to the skin.

Some formulations containing Analogue 1 were reported to be from slightly to moderately irritating to the skin, and a structurally similar isethionate (ethanesulfonic acid, 2-hydroxy-, sodium salt; CAS No. 1562-00-1) was reported as non-irritating (Burnett et al. 2017). Based on the available data, the potential of skin irritation for the assessed chemical cannot be ruled out.

Eye irritation

An eye irritation study (similar to OECD TG 405) was conducted on Analogue 1. The study was conducted in 6 New Zealand white rabbits, with 0.1 g of the test substance applied to one eye of all rabbits. The treated eyes in 3 rabbits were rinsed with water 4 seconds post application. The ocular irritation was evaluated for 7 days after exposure. No effects on the cornea were observed, but effects on the iris were observed in all animals, with one animal unable to react to light for up to 5 days. Conjunctival redness, chemosis and discharge of high severity were observed after treatment. At the 72-hour observations, effects on the iris and conjunctivae persisted in all animals but showed some degree of recovery. After 7 days, 1 animal with an unrinsed eye and 2 animals with rinsed eyes showed complete recovery. The

mean individual iris scores from gradings at 24, 48 and 72 hours were 2.0, 1.0, 1.0 respectively for the unrinsed eyes, and 1.0, 1.0, 0.3 respectively for rinsed eyes. The conjunctivae redness scores were 2.7, 1.7, 1.7 respectively for the unrinsed eyes, and 3, 1.3, 2.3 respectively for the rinsed eyes. The conjunctivae chemosis scores were 2.7, 2.0, 2.7, respectively for the unrinsed eyes, and 2.7, 2.0, 2.3 respectively for the rinsed eyes. The conjunctivae discharge scores were 1.7, 1.3, 1.7, respectively for unrinsed eyes, and 2.0, 0.7, 0.7 respectively for rinsed eyes.

Some formulations containing Analogue 1 were reported to be from non-irritating to severely irritating to the eyes, and the structurally similar chemical ethanesulfonic acid, 2-hydroxy-, sodium salt was reported as non-irritating (Burnett et al. 2017).

Based on the available data, the assessed chemical is irritating to the eyes and is classified as a Category 2A eye irritant according to the GHS criteria.

Sensitisation

Skin sensitisation

A skin sensitisation study (similar to OECD TG 406 – Magnusson-Kligman Test) was conducted on Analogue 1 in guinea pigs (Albino Dunkin-Hartley) (n = 10, 6F and 4M). The animals were given intradermal injection of 0.1 mL of the test substance (at 0.15% concentration). Seven days later, the test substance (at 20% concentration) was topically applied for 24 hours under occlusive conditions. Fourteen days after the topical induction, untreated sites of the animals were topically challenged with the test substance (at 5% concentration) for 24 hours under occlusive conditions, and the treated site was examined 24 and 48 hours after patch removal. A total of four challenges were done at weekly intervals. Following the first challenge, 1/10 animal showed very faint/faint erythema reaction at 24 hours and 2/10 animals showed the same reaction at 48 hours. Following the second challenge, 2/10 animals showed very faint/faint erythema reactions at 24 hours and 1 animal possibly showed the same reaction at 48 hours. Following the third challenge, no animals showed reactions. Following the fourth challenge, 1/10 animal showed and 1/10 animal possibly showed a very faint/faint reaction at 24 hours and 1/8 animal (2 animals died at this stage for a reason unrelated to the challenge, but attributed to lesions caused by the induction procedure) showed the same reaction at 48 hours. The number of very faint/faint reactions and the fact that some reactions were seen in the controls make the interpretation of the challenge results difficult and therefore, the study is inconclusive.

A second skin sensitisation study (similar to OECD TG 406 – Magnusson-Kligman Test) was conducted on Analogue 1 in guinea pigs (Albino Dunkin-Hartley) (n = 10, 4F and 6M). The animals were given intradermal injection of 0.1 mL of the test substance (at 0.2% concentration). Seven days later, the test substance (at 2.5% concentration) was topically applied for 48 hours under occlusive conditions. Thirteen to 14 days after the topical induction, untreated sites of the animals were topically challenged with the test substance (at 1% concentration) for 24 hours under occlusive conditions, and the treated site was examined 24 and 48 hours after patch removal. A total of 3 challenges were done at weekly intervals. Following the first challenge, 1/10 animal showed a very faint/faint erythema reaction at 24 hours and 1/10 animal showed the same reaction at 48 hours. Following the second challenge, no animals showed reactions. Following the third challenge, 2/10 animals showed very faint/faint reactions at 24 hours and 2/10 animals showed the same reaction at 48 hours. None of the control animals showed any reactions. Because the erythema observed in all treated animals were very faint/faint, and there were no increases in severity at 48 hours which is more indicative of sensitisation, the study did not show sufficient evidence that any of the animals had a genuine allergic response.

Some formulations containing Analogue 1 and the structurally similar chemical ethanesulfonic acid, 2-hydroxy-, sodium salt were reported to be not skin sensitising. Based on the available data, the assessed chemical is unlikely to be a skin sensitiser.

Repeat dose toxicity

Oral

In a repeated dose oral toxicity study (similar to OECD TG 407), Analogue 1 was administered to Sprague-Dawley rats (n = 10/sex/group) in the diet at 0%, 0.1%, 0.3%, and 1.0% (w/w) for 28 days. There were no unscheduled deaths or treatment-related clinical signs. Although some statistically significant changes in body weight gains were observed in the first half of the study, there were no consistent treatment-related changes throughout the study. Food and water consumption were decreased slightly in treated females, but no statistically significant changes in the absolute body weights were observed. One female from the high dose group had a nephroblastoma in the kidney but the presence of the tumour in a single treated animal was considered to be incidental and unrelated to treatment. There were no microscopic findings related to the treatment. The No Observed Adverse Effect Level (NOAEL) was considered to be 1.0% in the diet (10,000 ppm), the highest dose tested. Using the terminal mean body weights and the mean food consumption for males and females in the last week of the study, the NOAEL was calculated to be 627.2 mg/kg bw/day for males and 719.8 mg/kg bw/day for females.

Dermal

In a repeated dose dermal toxicity study (OECD TG 410), aqueous suspensions of Analogue 1 were applied to Sprague-Dawley rats (n = 10/sex/group) at 0, 80, 910 and 2,070 mg/kg bw/day for 28 days, under semi-occlusive conditions, for 6 hours per day.

No treatment-related signs of systemic toxicity were noted. One male in the mid dose group was found dead on Day 19, with the cause being attributed to physical trauma caused during the application process. Although there were transient low weight gains and weight loss attributed to the stress of the treatment procedure, no statistically significant changes in body weight and food and water consumption were observed over the total duration of the study. A statistically significant decrease in average haemoglobin level and a slight decrease in serum glucose concentration was observed in males in the high dose group. However, there was no evidence that these effects were treatment related. There was a slight increase in averaged heart weight relative to final body weight for males in the high dose group and an increase in averaged adrenal weight relative to final body weight for females in the same group. However, the organ weight data were within the historical control ranges and histopathological examination of the tissues did not show any adverse morphology. There were no treatment-related findings at necropsy.

In the low and mid dose groups, no signs of dermal irritation were observed in males, and very slight erythema was observed in 4/10 females in each of the groups during Week 1 only. Dermal irritation in the high dose group included very slight erythema in 2/10 males during Weeks 3 and 4, very slight erythema in up to 4/10 females during each week, very slight oedema in up to 5/10 females (5/10 in Week 1, 3/10 in Week 2, 1/10 in Week 3 and 0/10 in Week 4), and well-defined erythema in up to 5/10 females (5/10 in Week 1, 2/10 in Week 2, 2/10 in Week 3 and 0/10 in Week 4). Only the erythema effects in high dose females on Days 4-7 of Week 1 were statistically significant compared to the control. Histopathological and microscopic examinations of treated skin did not reveal treatment-related findings.

As there were no adverse systemic toxicity effects at up to the highest dermal dose tested, the systemic toxicity NOAEL for the test substance was 2,070 mg/kg bw/day.

Genotoxicity

The assessed chemical was found to be non-mutagenic in a bacterial reverse mutation assay (OECD TG 471) using TA98, TA100, TA1535, and TA1537 strains of *Salmonella typhimurium* and WP2*uvrA* strain of *Escherichia coli*.

Analogue 1 was found to be non-clastogenic to Chinese hamster ovary (CHO) cells in an *in vitro* mammalian chromosome aberration test (OECD TG 473). There were no biologically relevant increases in the frequency of chromosomal aberrations in cells treated at up to 150 µg/mL in the presence or absence of metabolic activation.

Analogue 1 was found to be non-mutagenic in an *in vitro* mammalian cell gene mutation test (OECD TG 476) using L5178Y mouse lymphoma cells. The cells were treated at up to 140 µg/mL concentration in the absence of metabolic activation (for 3 hour or 24 hours) or up to 150 µg/mL concentration in the presence of metabolic activation (for 3 hours). Although there was a significant linear increase trend in one experiment (3 hours treatment in the presence of metabolic activation), the mutant frequencies observed in cells were all less than the sum of mean control mutant frequency plus the global evaluation factor, indicating a negative result.

Analogue 1 was found to be non-genotoxic to human lymphocytes in an *in vitro* mammalian cell micronucleus test (OECD TG 487). There were no dose-dependent increases in frequencies of binucleate cells with micronuclei (MNBN cells), except for a statistically significant increase in one sample tested at the highest concentration tested (450 µg/mL) in the presence of metabolic activation. However, MNBN cell frequencies of the replicate samples at this concentration were within the historical values. Therefore, the study authors concluded that this single result was not of toxicological significance.

Reproductive and developmental toxicity

In a reproduction/developmental toxicity screening test (OECD TG 421), Analogue 2 was administered to female Wistar rats (n = 12/sex/group) by oral gavage at 0, 100, 300 and 1,000 mg/kg bw/day. Males were treated for 15 days pre-mating and during the mating period up to 1 day before necropsy and females were treated for the full duration of pre-mating, mating, gestation, and lactation period up to day 21 postpartum. The only mortality was one female in the high dose group due to dosing error. In animals from the mid and high dose group, a slight decrease in mean food consumption and mean body weight gain were observed, and mean body weight was slightly decreased in males. No other treatment-related effects on systemic and reproductive parameters were observed. No abnormalities were observed in pups. The NOAEL for systemic, reproductive and developmental toxicity was considered to be 1,000 mg/kg bw/day.

In a prenatal developmental toxicity study (OECD TG 414), Analogue 2 was administered to female Wistar rats (n = 22/group) by oral gavage at 0, 100, 300 and 1,000 mg/kg bw/day during gestation Days 6-20. There were no mortalities, treatment-related clinical signs or abnormal findings at necropsy. No treatment-related effects on developmental parameters were observed. The NOAEL for maternal and developmental toxicity was considered to be 1,000 mg/kg bw/day.

Environmental exposure

Significant release of the assessed chemical to the environment is not expected during reformulation, transport or storage. Release of the assessed chemical to the environment due to accidental spills is expected to be collected and disposed of in accordance with relevant Local, State, Territory and Federal regulations. Any unused product containing the assessed chemical is expected to be disposed of in accordance with relevant Local, State, Territory and Federal regulations.

Consumer end-use of the assessed chemical in personal care products (cosmetics) is expected to result in the release of the assessed chemical “down the drain” and into the sewers. Consequently, the assessed chemical will be treated at sewage treatment plants (STPs) before release to surface waters.

Environmental fate

Partitioning

The assessed chemical is readily soluble in water (water solubility = 1.29 g/L at 20°C) and is surface active (surface tension = 33.5 mN/m at 20°C). Thus, it is expected to partition to the phase boundary when released to the environment. The assessed chemical is expected to have low mobility in soil based on its high log Koc value (log Koc = 3.2).

Due to its very slight volatility (vapour pressure < 8.4 × 10^{-10} kPa at 20 °C), the assessed chemical is not expected to partition to air.

Degradation

Based on measured degradation in water of an acceptable read across chemical, the assessed chemical is categorised as not persistent.

In a supplied OECD 301B ready biodegradation screening test conducted in water, a UVCB substance (Analogue 2) containing the assessed chemical as its main components, showed 78% degradation after 28 days, and the 10-day-window criterion was satisfied. Therefore, the assessed chemical is considered readily biodegradable.

In another supplied biodegradation screening test conducted in water according to the Standard Operating Procedure 05201 in Operation of OECD Screening Test, the Analogue 2 containing the assessed chemical as its main components, showed 99.2% primary degradation after 2 days, and 99.6% degradation in 14 days. Therefore, the assessed chemical is considered biodegradable.

Bioaccumulation

Based on weight of evidence, the assessed chemical is categorised as not bioaccumulative.

No bioaccumulation study was provided for the assessed chemical. The assessed chemical is a surfactant and most surfactants tend to be retained on epithelial surfaces, rather than cross cellular membrane and bioaccumulate (de Oude 1992; McWilliams and Payne 2001). Hence, bioaccumulation for most classes of surfactants is generally below the level of concern (McWilliams and Payne 2001). In a published study, a 28 d BCF (bioaccumulation factor) of 255 L/kg was determined for dodecanoic acid, sodium salt (CAS RN: 629-25-4), which is structurally similar to the assessed chemical (van Egmond et al, 1999).

In addition, low bioaccumulation potential of the assessed chemical is demonstrated via the tiered approach in accordance with ECHA Annex XI, section 1.2 “weight of evidence”. The approach consists of (1) Tier 1: Deriving the baseline screening bioconcentration factors (BCF) through the use of *in-silico* approaches (using OECD Toolbox v4.5 and CATALOGIC v5.16.1 software); and (2) Tier 2: Refined BCF assessment using the BIONIC (v3) model adapted for anionic surfactants, in conjunction with the *in-vitro* assay for determination of biotransformation (OECD 319B) and membrane-water partitioning.

The initial screening (Tier 1) showed that alkyl isethionates have fast metabolic half-lives and low bioaccumulation potential, specifically for anionic surfactants with alkyl chain lengths < C18.

Estimations from BIONIC model (Tier 2) showed predicted BCF values ranging between 22 to 1,134 L/kg for alkyl isethionates with C8-C18 chain lengths. These values were estimated without accounting for the decrease in bioavailability caused by adsorption and rapid biodegradation, which could further lower the BCF values. These predicted BCF values are well below the domestic bioaccumulation threshold of 2,000 L/kg. Therefore, the assessed chemical is considered not bioaccumulative.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated assuming 100% of the introduction volume is released into sewage treatment plants (STP) over 365 days per annum. The extent to which the assessed substance is removed from the effluent in STP processes is based on its physicochemical properties and biodegradability, modelled by SimpleTreat 4.1 (Struijs 2014).

In Australia, about 20% of sewage is treated to primary levels which then discharged to ocean, and 80% of Australian sewage is treated to at least secondary levels which then discharged to both ocean and rivers (Blue Environment 2020). Removal at the primary stage, and total removal percentages through STP were calculated. A dilution factor of 1 was applied to river discharge and a dilution factor of 10 was applied to ocean discharge (EPHC 2009). PEC calculations for river and ocean discharges are summarised in the table below:

Total Annual Import Volume	195,000	kg/year
Proportion expected to be released to sewer	100%	
Days per year where release occurs	365	days/year
Emission rate	534.25	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal from primary treatment	10.97%	Mitigation
Removal from secondary treatment	89.75%	Mitigation
Daily effluent production	5,085	ML/day

PEC - River	10.77	µg/L
PEC – Ocean (primary treatment)	9.35	µg/L
PEC – Ocean (secondary treatment)	1.08	µg/L

Environmental effects

Effects on aquatic life

Acute toxicity

The following measured median lethal concentration (LC50) and median effective concentration (EC50) values for model organisms were supplied for the assessed chemical and Analogue 2 (containing the assessed chemical as its main component):

Taxon	Endpoint	Method
Fish	Analogue 2 96 h LC50 > 25 mg/L[1]	*Oncorhybchus mykiss* (rainbow trout) Mortality OECD TG 203 Semi-static conditions Measured concentration
Invertebrate	48 h EC50 = 12.4 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Semi-static conditions Measured active ingredient concentration
Algae	72h ErC50 = 20 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static conditions Measured active ingredient concentration
Microorganisms	Analogue 2 Total respiration: 3 h IC50 = 336 mg/L Heterotrophic respiration: 3 h IC50 = 989 mg/L	*Activated sludge from a STP* OECD TG 209 Respiration inhibition Static conditions Nominal concentration

[1]*Only 10% mortality was observed at highest test concentration of 100 mg/L nominal concentration or equalled to 25 mg/L measured concentration. No mortality was observed in any other test concentrations.*

Chronic toxicity

The following measured no effect concentration (NOEC) and 10th percentile effective concentration (EC10) values for model organisms were supplied for the assessed chemical and the read across chemical.

Taxon	Endpoint	Method
Fish	Analogue 2 32 d NOEC = 0.11 mg/L	*Pimephales promelas* (fathead minnow) Survival OECD TG 210 Flow-through conditions Measured concentration
Invertebrates	21 d EC10 = 7.03 mg/L	*Daphnia magna* (water flea) Reproduction OECD TG 202 Semi-static conditions Measured active ingredient concentration
Algae	72h ErC10 = 5.57 mg/L	*Raphidocelis subcapitata* (green algae) Growth rate OECD TG 201 Static conditions Measured active ingredient concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 11 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most sensitive chronic endpoint value, which is for fish (32 d NOEC = 0.11 mg/L). An assessment factor of 10 was applied to this endpoint as acute and chronic toxicity data are available for all three trophic levels (EPHC, 2009).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022) is presented below:

Persistence

Not Persistent (Not P). Based on measured degradation study, the chemical is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on weight of evidence, the chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available acute ecotoxicity values above 1 mg/L and chronic ecotoxicity values above 0.1 mg/L, the chemical is categorised as Not Toxic.

Environmental risk characterisation

The assessed chemical is not PBT and is hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed chemical to water:

Compartment	PEC	PNEC	RQ
River	10.77 µg/L	11 µg/L	0.979
Ocean	9.35 µg/L	11 µg/L	0.850

For the river and ocean compartments, an RQ less than 1 indicates that introduction of the assessed chemical, in line with the defined scope of assessment, is not expected to pose a risk to the environment. As such, the risk from the introduction of the assessed chemical can be managed, based on consideration of the environmental hazard characteristics and estimated releases.

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