File No: STD/1677

March 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fatty acids, C8-16, 2-sulfopropyl esters, sodium salts

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1677	A.S. Harrison & Co Pty Ltd	Fatty acids, C8-16, 2-sulfopropyl esters, sodium salts	Yes	≤ 100 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard Classification	*Hazard Statement*
Acute (Category 3)	H402 – Harmful to aquatic life

Human Health Risk Assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner with appropriate safety information on the packaging, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin corrosion/irritation (Category 2): H315 – Causes skin irritation
  - Serious eye damage/eye irritation (Category 2A): H319 – Causes serious eye irritation

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed, automated processes if possible
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation and end-use:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation:
  - Impervious gloves
  - Protective clothing
  - Safety glasses or goggles

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during end-use:
  - Impervious gloves

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- Formulators should take into account the potential for the notified chemical to cause eye and skin irritation when formulating cosmetic products containing the notified chemical.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the

notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the notified chemical is intended for use in eye cosmetics;
- additional information has become available to the person as to skin or eye irritation effects from consumer use of products containing the chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a cosmetic ingredient, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
A.S. Harrison & Co Pty Ltd (ABN: 89 000 030 437)
75 Old Pittwater Road
BROOKVALE NSW 2100

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) - Similar to a chemical previously assessed by NICNAS (STD/1342; CAS Number 928663-45-0).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: structural formula, molecular weight, analytical data, degree of purity, impurities and additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, autoignition temperature, explosive properties, oxidising properties and all (eco)toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
Iselux SCMI

CAS NUMBER
2244880-58-6

CHEMICAL NAME
Fatty acids, C8-16, 2-sulfopropyl esters, sodium salts

OTHER NAMES
Sodium Cocoyl Methyl Isethionate
Pureact SCMI-85
Pureact SCMI
SCMI

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
< 500 g/mol

ANALYTICAL DATA
Reference NMR, IR, LC-MS, and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: solid off-white flakes

Property	*Value*	*Data Source/Justification*
Melting Point	132 - 140 °C	Measured
Boiling Point	321 - 323 °C with decomposition	Measured
Density	1,162 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 1× 10^{-5} kPa at 20 °C	SDS
Water Solubility	> 347.1 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality, but hydrolysis is not expected to occur within the environmental pH range of 4-9
Partition Coefficient (n-octanol/water)	Not determined	Cannot be measured due to the surfactant nature of the notified chemical
Surface Tension	29.7 mN.m^{-1} at 20 °C	Measured
Adsorption/Desorption	log K_{oc} < 1.3 at 25 °C	SDS Analogue chemical 1 (used in STD/1342)
Dissociation Constant	Not determined	The notified chemical is expected to fully dissociate under environmental conditions (pH 4-9)
Flash Point	228 °C (closed cup)	SDS Analogue chemical 1 (used in STD/1342)
Flammability	Not highly flammable	Measured
Autoignition Temperature	Not determined	Solid with a melting point ≤ 160 °C
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported in its neat form for reformulation into finished rinse-off cosmetic products at ≤ 50% concentration and finished leave-on cosmetic products at ≤ 17% concentration. The notified chemical will also be introduced as a component of finished rinse-off cosmetic products at ≤ 50% concentration and finished leave-on cosmetic products at ≤ 17% concentration.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 100	≤ 100	≤ 100	≤ 100	≤ 100

PORT OF ENTRY
Melbourne, Sydney, Brisbane, Perth and Adelaide

TRANSPORTATION AND PACKAGING

The notified chemical in its neat form will be mainly imported in 500 kg flexible intermediate bulk container (FIBC) baffle bags. The notified chemical in its neat form may also be imported in 90.7 kg fibre drums or smaller plastic pails. Finished cosmetic products containing the notified chemical will be introduced in packaging suitable for retail sale (≤ 500 mL).

USE

The notified chemical will be used as a cosmetic ingredient in a variety of rinse-off cosmetic products at ≤ 50% concentration and leave-on cosmetic products at ≤ 17% concentration. Products containing the notified chemical will include shampoos, conditioners, bath gels/foams, liquid soaps, facial cleanser, shave foams/gels and secondary sunscreens. Products to be used as secondary sunscreens will include moisturisers, sun-bathing products, lip balms, lipsticks and other general make-up products. The notified chemical will not be used in eye cosmetics.

OPERATION DESCRIPTION

Reformulation

Reformulation of the neat notified chemical into finished cosmetic products may vary depending on the type of product, and may involve both automated and manual transfer steps. It is expected that the reformulation processes will involve blending operations that will be highly automated and occur in a fully enclosed/contained environment, followed by automated filling (using sealed delivery systems) of the reformulated end-use products into containers of various sizes.

End-use

Finished rinse-off cosmetic products at ≤ 50% concentration and finished leave-on cosmetic products at ≤ 17% concentration will be used by consumers and professionals (such as beauticians and hairdressers). Depending on the nature of the product, application of the products could be by hand, sprayed or through the use of an applicator.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Dock worker (stevedore)	1	1 - 2
Transport	10 – 20	6 - 8
Reformulation	2	6 - 8
Quality control	2	6 - 8
Retail	1	8 - 12
End users (professionals)	6 – 8	Up to 200

EXPOSURE DETAILS

Transport and storage

Transport, storage and warehouse workers may come into contact with the notified chemical (in neat form or at ≤ 50% concentration in final formulated products), only in the unlikely event of an accidental rupture of containers.

Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified chemical at ≤ 100% concentration may occur during weighing and transfer stages, blending, quality control analysis, and cleaning and maintenance of equipment. The notifier states that exposure is expected to be minimised through the use of local ventilation and personal protective equipment (PPE) such as protective clothing, eye protection and impervious gloves.

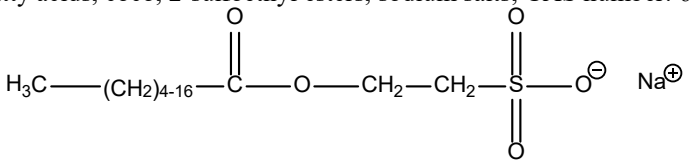
End use professionals
Workers involved in professions which involve application of cosmetic products containing the notified chemical to clients (such as beauticians and hairdressers) may be exposed to the notified chemical at ≤ 50% concentration. The principal route of exposure will be dermal, while ocular and inhalation exposure are also possible. Such professionals may use some PPE to minimise repeated exposure and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemical at ≤ 50% concentration through the use of a wide range of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure (e.g. through the use of spray products) are also possible.

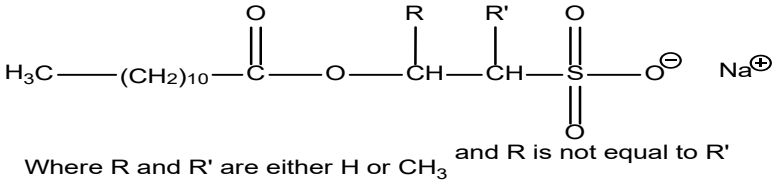
6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on structurally similar analogue chemicals 1 (used in STD/1342 as an analogue) and 2 (previously assessed chemical in STD/1342), are summarised in the following table.

Endpoint	*Test substance*	*Result and Assessment Conclusion*	*Reference*
Rat, acute oral toxicity	Analogue chemical 1 (47.5% concentration)	LD50 > 5000 mg/kg bw; low toxicity	Hazleton (1986a)
	Analogue chemical 1 (15% concentration)	LD50 > 5000 mg/kg bw; low toxicity	IUCLID (2006) JACT (1993)
	Analogue chemical 1 (20% concentration)	LD50 = 8,000 mg/kg bw; low toxicity	IUCLID (2006)
Rabbit, skin irritation	Analogue chemical 1 (1 to 93.7% concentration)	slight to moderately irritating	IUCLID (2006) JACT (1993)
Human, 14 Day Cumulative Irritation Test (occlusive)	Analogue 2 (concentration unknown)	irritating	Essex (2007)
Rabbit, eye irritation	Analogue chemical 1 (47.5% concentration)	irritating	Hazleton (1986b)
	Analogue chemical 1 (2.5 to 24.5% concentration)	slightly irritating to irritating	IUCLID (2006) JACT (1993)
Guinea pig, skin sensitisation – modified Buehler test	Analogue chemical 1 (induction concentration from 1 to 66%)	no evidence of sensitisation	IUCLID (2006) JACT (1993)
Rat, repeat dose oral toxicity – 28 days	Analogue chemical 1 (90% concentration)	NOAEL > 1,000 mg/kg bw/day	IUCLID (2006)
Rat, repeat dose dermal toxicity – 10 days	Analogue chemical 1 (72.4% concentration)	NOAEL > 4,350 mg/kg bw/day	IUCLID (2006) JACT (1993)
Rat, repeat dose dermal toxicity – 28 days	Analogue chemical 1 (72.4% concentration)	NOAEL > 2,070 mg/kg bw/day	IUCLID (2006) JACT (1993)
Mutagenicity – bacterial reverse mutation	Analogue chemical 1 (68.7% and 72.45% concentration)	non mutagenic	IUCLID (2006) JACT (1993)
Genotoxicity – *in vitro* cell gene mutation assay in Chinese hamster ovary cells	Analogue chemical 1 (72.45% concentration)	non genotoxic	IUCLID (2006) JACT (1993)

Analogue chemical 1 (fatty acids, coco, 2-sulfoethyl esters, sodium salts; CAS number: 61789-32-0).



Analogue chemical 2 (dodecanoic acid, methyl-2-sulfoethyl ester, sodium salt (1:1), CAS No: 928663-45-0)



Toxicokinetics
Given the low molecular weight (< 500 g/mol) and moderate water solubility (347.1 g/L at 30 °C) of the notified chemical, absorption across biological membranes may occur.

In an *in vitro* study with an analogue chemical, dodecanoic acid, 2-sulfoethyl ester, sodium salt (1:1), (CAS No: 7381-01-3) with human skin, an increasing rate of absorption was recorded over time with a maximum rate of 30.1 ± 13.6 μg/cm^2 observed 48 hours after application (IUCLID, 2006). A further two *in vivo* studies in rats have been reported with this analogue; in one of the experiments the level of absorption was measured 24 hours after exposure using ^{14}C isotope labelling which found absorption rates of between 0.1 to 0.3 μg/cm^2 (IUCLID, 2006). In the second experiment where the rats were exposed for 12 hours the absorption rate was found to plateau after 3 hours at a rate of 0.6 μg/cm^2 (IUCLID, 2006).

Acute toxicity
No studies were submitted on the acute toxicity of the notified chemical.

Analogue chemical 1 when tested at up to 47.5% concentration was found to be of low acute oral toxicity in rats. No acute dermal toxicity data are available for the analogue chemicals. Repeat dose dermal toxicity studies conducted with analogue chemical 1 showed low dermal toxicity.

Irritation and Sensitisation
No studies were submitted for the notified chemical.

Slight to moderate skin irritation was reported in studies conducted in rabbits with analogue chemical 1 at concentrations ranging from 1 to 93.7% concentration. Slight skin irritation was reported in a test with analogue chemical 1 at 1% concentration. This test also involved a 30 min UV irradiation on one of the test sites. No significant difference in irritation effects was noted between the irradiated and non-irradiated sites. In two skin irritation studies conducted on analogue chemical 1 at 5% concentration with a 24 hour application, one study showed slight irritation while the other showed moderate irritation. However, in the study which was found to be moderately irritating, the irritation scores with the abraded skin were significantly higher than those seen in the non-abraded skin, with the effects seen in the non-abraded skin indicative of only slight irritation. A 24 hour semi-occluded application of analogue chemical 1 at 15% concentration showed moderate irritation. Moderate irritation was also observed in a skin irritation study with analogue chemical 1 at 93.7% concentration.

Analogue chemical 1 has been tested in a number of eye irritation studies in rabbits at concentrations ranging from 2.5 to 47.5%. At 47.5% concentration, analogue chemical 1 was found to be an eye irritant. Although effects were present at the end of the 7 day study period, all of the symptoms had reduced from the maximum values and in 2/6 animals all symptoms were resolved by Day 7. The next highest concentration where information is available on analogue chemical 1 is 24.5%, where corneal opacity was observed in 3/3 animals and conjunctival effects in 2 animals at the 24 hour observation with all symptoms clearing by day 14. In another two different studies with analogue chemical 1 at 15% concentration, it was found to be an irritant in one study where 0.1 mL of the test substance was placed in the eye, but only slightly irritating in the other study where a volume of 10 μL was used. At a concentration of 5%, analogue chemical 1 was described as “minimally irritating” to rinsed eyes and “mildly irritating” to unrinsed eyes. At 2.5% concentration, analogue chemical 1

was found to be slightly irritating to the eyes. Overall, based on the results of the study conducted with analogue chemical 1 at 47.5% concentration, analogue chemical 1 and by inference the notified chemical, warrants classification as a Category 2A Eye Irritant under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

No evidence of sensitisation was noted in three studies in guinea pigs for analogue chemical 1 at induction concentrations ranging from 1 to 66%.

Repeated Dose Toxicity
No data were submitted for the notified chemical

In a 28 day feeding study in rats with analogue chemical 1 at 90% concentration in the diet, the No Observed Adverse Effect Level (NOAEL) was established to be > 1,000 mg/kg bw/day, based on the absence of treatment related effects up to the highest dose tested.

In a 10 day and a 28 day repeated dose dermal toxicity studies in rats with analogue chemical 1 at 72.4% concentration, the NOAEL was established as > 4,350 mg/kg bw/day and > 2,070 mg/kg bw/day, respectively, based on the absence of systemic effects up to the highest dose tested.

Mutagenicity
No data were available on the genotoxic potential of the notified chemical.

Analogue chemical 1 at 68.7% and 72.45% concentration was found to be negative in separate bacterial reverse mutation assays. Analogue chemical 1 at 72.45% concentration was negative in an *in vitro* cell gene mutation test in Chinese hamster ovary cells.

Observations on Human Exposure
In a 14 day cumulative irritation test using human volunteers, analogue chemical 2 (concentration not known) was found to show irritation from day 4 onwards. In 15 out of the 20 test subjects an irritation score of 3 was assigned indicating marked erythema. In the study further patch testing at the test site was terminated if a score of 3 or more occurred. Based on the results of this study, analogue 2 and by inference the notified chemical, warrants classification as a Category 2 Skin Irritant under the GHS.

A 4% aqueous solution of a gel cleanser containing 15% analogue chemical 1 was found to be non-irritating in a 48 hour patch test with 12 subjects (IUCLID, 2006; JACT, 1993). In six modified soap chamber tests with analogue chemical 1 at 8% concentration, it was found to be slightly irritating in five of the studies and irritating in the other (IUCLID 2006; JACT 1993). In one modified soap chamber test where analogue chemical 1 was found to be irritating it was noted that the cold and dry climatic conditions at the time might have aggravated the irritation. A 21 day cumulative irritation test on 35 subjects with analogue chemical 1 at 0.1% concentration produced only very slight signs of irritation (IUCLID 2006; JACT 1993). A repeat application patch test (3 applications of 24 hours each) at concentrations of 0.2, 0.4 and 1.0% conducted with 10 volunteers produced slight irritation (IUCLID, 2006; JACT, 1993). However, in a 14 day irritation study using 19 subjects, a 4-6% aqueous solution of a gel cleanser containing 15% analogue chemical 1 produced moderate to severe irritation (JACT, 1993). The other ingredients in the gel cleanser were not specified and therefore it is not confirmed that analogue chemical 1 or other ingredients produced the irritant effects in this study.

Four human repeated insult patch tests (HRIPT) were conducted with personal washing bars containing 49.87% analogue chemical 1 at concentrations up to 8% (4% analogue chemical 1) and no evidence of sensitisation was noted (JACT, 1993). In another HRIPT a skin cleanser with analogue chemical 1 at 17% was applied to 96 test subjects over a period of 3 weeks during the induction phase (IUCLID 2006; JACT 1993). After the challenge application (dose not stated), 12 subjects showed very slight signs of irritation and 2 had delayed mild to moderate erythema, which was not present in a follow up test on these 2 subjects. The test substance containing analogue chemical 1 at 17% was not sensitising. In another HRIPT, a 2% solution of a soap containing 47.5% analogue chemical 1 was found to have very low to nil potential for irritation and sensitisation (IUCLID, 2006; JACT, 1993).

Health Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2A)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the critical health effects of the notified chemical are skin and eye irritation.

Reformulation

During reformulation, workers may be at risk of skin and eye irritation when handling the neat notified chemical. The stated use by the notifier of enclosed, automated processes and PPE (i.e., protective clothing, eye protection and impervious gloves) should minimise the potential for worker exposure.

Therefore, provided the stated control measures are in place to minimise worker exposure, the risk to the health of workers from the notified chemical during reformulation is not considered to be unreasonable.

End-use

Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical to clients (such as beauticians and hairdressers) may be exposed to the notified chemical at ≤ 50% concentration. At the proposed end-use concentrations the risk of skin and eye irritation cannot be ruled out. Good hygiene practices, such as hand washing that may occur following application of the product is expected to reduce the risk of skin irritation by minimising the skin contact time. In addition, appropriate labelling of the product to warn against the possibility of irritation is expected to further lower the risk to these workers (i.e. use of gloves during application of products containing the chemical), if used at high concentrations. Under normal circumstances ocular exposure to the products containing the notified chemical is not expected.

Therefore, the risk to professional end-users (such as beauticians and hairdressers) exposed to the notified chemical at ≤ 50% concentration is not considered to be unreasonable provided appropriate labelling of the products is in place to warn against the possibility of skin and eye irritation.

6.3.2. Public Health

Members of the public may experience repeated exposure to the notified chemical through the use of cosmetic products containing the notified chemical at ≤ 17% concentration in leave-on cosmetic products and at ≤ 50% concentration in rinse-off cosmetic products. Based on the available information, the critical health effects of the notified chemical are skin and eye irritation. Systemic effects from repeated exposure are not expected.

Irritation

At the proposed end-use concentrations of the notified chemical in cosmetic products the risk of skin and eye irritation cannot be ruled out. The greatest risk of skin irritation is expected from leave-on cosmetic products. For rinse-off cosmetic products the reduced contact time with the skin is expected to reduce the potential for irritation. In addition, appropriate labelling of the product to warn against the possibility of irritation is expected to lower the risk to consumers, if used at high concentrations. Under normal circumstances ocular exposure to the products containing the notified chemical is not expected. However, accidental eye exposure from rinse-off haircare products is possible.

According to the notifier, the eye and skin irritation classification of the notified chemical will be made transparent through product information sheets and the SDS. The risk assessment also recommends that formulators of cosmetic products should take into account the potential for the notified chemical to cause irritation when formulating cosmetic products containing the notified chemical.

Therefore, when used in the proposed manner with appropriate safety information on the packaging, the risk to the public associated with eye and skin contact with the notified chemical in leave-on and rinse-off cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia neat for reformulation into cosmetic products, or as a component of finished cosmetic products at ≤ 50% concentration. Significant release to the environment from transport and storage is not expected. In the event of accidental spillage, spills containing the notified chemical are expected to be collected and be disposed of to landfill in accordance with local government regulations.

The reformulation processes will involve blending operations that will be highly automated and occur in a fully enclosed/contained environment. Therefore, significant release of the notified chemical from this process is not expected. The notifier has indicated that any wastes containing the notified chemical generated during reformulation may be collected and returned to the mixing vat, or disposed of to landfill in accordance with local government regulations. The notifier estimates < 1% of the import volume may be released to sewer from cleaning and maintenance operations of the blending and bottling equipment.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewer as a result of its use in cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that a small proportion of the notified chemical (< 2% of the total import volume) will remain in import containers and end-use containers once the consumer products are used up. Wastes and residue of the notified chemical in empty containers will either share the fate of the container and be disposed of to landfill, or be released to sewer when containers are rinsed, before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in cosmetic products in Australia, the majority of the notified chemical is expected to enter the sewer system before potential release to surface waters nationwide. A biodegradability study conducted on an acceptable analogue to the notified chemical (analogue chemical 1) and assessed in STD/1342, determined that the analogue is readily biodegradable.

Due to the anionic surfactant properties of the notified chemical, a significant amount of the notified chemical is expected to sorb to sludge in STPs. The notified chemical in sewage sludge is expected to be disposed of to landfill, or applied to land when sludge is used for soil remediation. Notified chemical released to surface waters is expected to partition to suspended solids and organic matter, and disperse. Consequently, the notified chemical is not expected to be significantly bioavailable. Based on its surface activity and expected biodegradability, the notified chemical is not expected to bioaccumulate. The notified chemical is expected to ultimately degrade through biotic and abiotic processes to form water and oxides of carbon and sulfur.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified chemical into sewer systems nationwide and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	100,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	273.97	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML

Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	56.18	µg/L
PEC - Ocean:	5.62	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 7.303 µg/L may potentially result in a soil concentration of approximately 486.9 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 24.34 mg/kg and 48.69 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data was provided for the notified chemical. The results from ecotoxicological investigations conducted on an acceptable analogue to the notified chemical (analogue chemical 1), previously assessed in STD/1342, are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 29.3 mg/L	Harmful to fish
Daphnia Toxicity	EC50 (48 h) = 257.86 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity	IC50 (96 h) > 1,000 mg/L	Not harmful to algae

Based on the above ecotoxicological endpoints for analogue chemical 1, the notified chemical is expected to be harmful to fish. Therefore, the notified chemical is classified as 'Acute Category 3: Harmful to aquatic life' according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). The notified chemical is readily biodegradable and is not expected to bioaccumulate. Therefore, the notified chemical is not formally classified under the GHS for its long-term hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated based on the most sensitive endpoint (EC50 for fish toxicity). An assessment factor of 100 was used as three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	29.30	mg/L
Assessment Factor	100.00	
Mitigation Factor	1.00	
PNEC:	293.00	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	56.18	293	0.19
Q - Ocean:	5.62	293	0.019

The risk quotient (Q=PEC/PNEC) has been calculated based on the assumption of a worst case scenario of complete release into the waterways. The risk is likely to be lower due to the mitigating effects of biodegradation. The calculated Q value indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in the aquatic environment based on the proposed annual importation volume and use pattern. The notified chemical is expected to be readily biodegradable, and is not expected to be bioaccumulative.

Therefore, on the basis of the PEC/PNEC ratio, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 132 - 140 °C

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	Capillary method used. Change in test substance translucency was noted at approx. 50 °C; the study authors state that this observation suggests softening of the test sample. Bubble formation in the test sample was noted at approx. 127 °C.
Test Facility	DEKRA (2018)

Boiling Point 321 - 323 °C with decomposition

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Differential scanning calorimetry used. Residue ranging in colour from off white-grey to black was observed by the study authors after each experimental run.
Test Facility	DEKRA (2018)

Density 1,162 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Pycnometer method used.
Test Facility	DEKRA (2018)

Water Solubility > 347.1 g/L at 30 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method. Deviations from the OECD guidelines are as follows: Only one test solution of concentration (347.1 g/L) was evaluated as there were indications of insolubility in the initial testing. The test solution evaluated was fully saturated as indicated by a white solid in the base of the centrifuge tube after 1 hour of centrifuging. A solution at 3-5 times saturation value was not used as this created a semi-mobile paste which was unable to be passed through a HPLC column.
Test Facility	DEKRA (2018)

Surface Tension 29.7 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions EC Council Regulation No 440/2008 A.5 Surface Tension
Remarks	Concentration: 1 g/L
Test Facility	DEKRA (2018)

Flammability Not highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks	The study authors note that test substance melted and ignited with a medium orange flame which did not propagate.
Test Facility	DEKRA (2018)

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