File No: EX/232 (LTD/2072)

January 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Glycerides, C_{16-18} mono-, di- and tri-, hydrogenated, citrates, 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 Agriculture, Water and the Environment.

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:

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Director
NICNAS

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This assessment report is for an extension of original assessment certificate for Glycerides, C_{16-18} mono-, di- and tri-, hydrogenated, citrates, sodium salts. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading *'Extension Application'* in the respective sections.

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
EX/232 (LTD/2072)	Unilever Australia Ltd	Glycerides, C_{16-18} mono-, di- and tri-, hydrogenated, citrates, sodium salts	ND*	≤ 1 tonne per annum	Cosmetic ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
As only limited toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 as a cosmetic ingredient up to 10% concentration, 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, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

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, where possible
  - Adequate general and local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure when handling the notified chemical during reformulation:
  - Avoid breathing vapours, mists or dusts

- 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:
  - Safety glasses
  - Protective gloves and clothing

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.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

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 importation volume exceeds one tonne per annum notified chemical;
- the final use concentration of the notified chemical exceeds 10% in cosmetic products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from 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.

Extension Application:
The applicant for the extension application has provided a SDS for the notified chemical. The accuracy of the information on the SDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Holder of Original Assessment Certificates (LTD/2072)
L'Oréal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

Applicant for an Extension of the Original Assessment Certificates:
Unilever Australia Ltd (ABN: 66 004 050 828)
Level 17, 2 Park Street
SYDNEY NSW 2000

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, use details, site of manufacture/reformulation, identity of manufacturer, identity of analogues and references.

Extension Application
Data items and details exempt from publication include: import volume and details of use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physical and chemical properties except melting point and boiling point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
United States of America (USA) (1989, 1994)
European Union (2017)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Glycerides, C_{16-18} mono-, di- and tri-, hydrogenated, citrates, sodium salts

CAS NUMBER
91744-39-7

CHEMICAL NAME
Glycerides, C_{16-18} mono-, di- and tri-, hydrogenated, citrates, sodium salts

MOLECULAR WEIGHT
> 500 g/mol

The notified chemical is a substance of Unknown or Variable composition, Complex reaction products and Biological materials (UVCB).

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Ivory coloured solid with a fatty odour.

Property	*Value*	*Data Source/Justification*
Melting Point	58 °C	Measured
Boiling Point	Not determined, decomposes over 230 °C	Measured
Density	1032 kg/m^3 at 22 °C	SDS
Vapour Pressure	3.93 × 10^{-27} kPa at 25°C	Estimated using QSAR for the main constituent
Water Solubility	14 mg/L at 25 °C	Modelled (EPIwin version 4.11)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but half-lives at pH 7 were calculated to be > 1 year (EPIwin version 4.11)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on hydrophobic and anionic properties
Dissociation Constant		Contains anionic functionality which will be dissociated in the environmentally relevant pH range (4–9)
Particle Size	Pellets	SDS
Flash Point	> 100 °C	SDS
Flammability	Not determined	May be combustible
Auto-ignition Temperature	Not determined	Expected to be > 100 °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 oxidative properties

DISCUSSION OF PROPERTIES

For details of tests on melting and boiling points, refer to Appendix A. Quantitative structure-activity relationship (QSAR) modelling was used to estimate certain physical and chemical properties as indicated above.

Reactivity

The notified chemical is expected to be stable under normal conditions of use. The notified chemical is a surfactant with limited water solubility (modelled data).

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 into Australia as the chemical itself (in neat form) or as a component of finished cosmetic products at ≤ 10% concentrations.

Extension Application

The notified chemical will be imported into Australia as a component of finished cosmetic products of the same type as in the original notification. The neat form of the notified chemical may be introduced at a later stage for reformulation.

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

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

Extension Application
The total introduction volume listed in the original assessment is unchanged. The quantity of notified chemical imported by the Extension applicants will be included in the introduction volume of the original assessment.

PORT OF ENTRY
Sydney or Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be shipped to Australia by sea in containers. It will be packaged in 25 kg bags and transported on shipment pallets with multiple pallets per container. The containers will be transported to the appropriate distribution centres and stored on pallets in fully bund areas.

Finished cosmetic products containing the notified chemical will be shipped to Australia by sea in containers. The products will be packed in dozens inside a shipper, with multiple shippers per pallet and multiple pallets per container. The containers will be transported to the appropriate distribution centres and distributed on individual orders for delivery to major retailer warehouses. The end use consumer containers have sizes up to 500 mL and may be bottles or tubes made mainly from high-density polyethylene (HDPE).

USE
The notified chemical will be used as a component in leave on and rinse off cosmetic products at concentration ≤ 10 %, which may include aerosol sprays.

OPERATION DESCRIPTION

Transport and storage
Approximately ten dockside and warehouse workers will be involved in transporting the notified chemical or finished cosmetic products containing the notified chemical, from the wharf to the distribution centres and placing the shipment pallets of products into the warehouse. These workers may handle monthly shipments for four hours per day. A further two workers in the warehouse will be involved in transferring the pallets and operating for stock to distributors at distribution depots.

Reformulation and blending
For reformulation and blending purposes, store persons will receive and store the notified chemical in the raw material store.

Chemists, wearing protection for eyes and skin, will take samples at various stages and test the samples for quality assessment (QA) purposes. The samples will be taken using scoops and later retained for reference purposes.

Compounders will be issued from store persons with quantities of the notified chemical for production as required, once cleared by QA. The compounders, wearing safety glasses with shields, gloves, apron or coverall, will weigh appropriate amounts of the notified chemical into containers and add directly into flame proof mixing tanks. Mixing and dispensing will be carried out in closed systems with flame proof mixers and pumps designed not to create aerosols or dusts and earthed for static discharges.

End use
Finished cosmetic products containing the notified chemical at ≤ 10% concentration will be used by professional end users (such as beauticians and hairdressers). Depending on the nature of the cosmetic product, application may be done 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)*
Dockside and Warehouse Workers	4	12

Compounders	8	12
Chemists	3	12
Packers (Dispensing and Capping)	8	12
Store Persons	4	12
Professional End Users	8	365

EXPOSURE DETAILS

Transport and Storage
Dockside and warehouse workers may come into contact with the notified chemical at up to the neat form, only in the unlikely event of an accidental rupture of containers. Workers are expected to wear personal protective equipment (PPE) including uniforms, gloves, protective glasses and safety shoes to minimise the potential for exposure.

Reformulation
During the process, workers (including chemists, compounders, store persons and packers) may be exposed to drips, spills and possible aerosols of the notified chemical at various concentrations up to the neat form. The main route of exposure is expected to be dermal. The blending process is expected to be automated and in a closed vessel, and workers are expected to wear PPE, minimising potential for exposure.

Professional use
Dermal exposure to the notified chemical at ≤ 10% concentration in finished cosmetic products may occur in professional end users where the services provided involve the application of the products to customers. The main route of exposure will be dermal, but ocular and inhalation exposure are also possible. Use of PPE by these workers is mostly expected to minimise repeated exposure and good hygiene practices are usually in place. If PPE is used, exposure of professional 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 ≤ 10 % concentration through daily use of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly if products are applied by spray. Incidental ingestion of the products is also possible from facial use.

Dermal absorption
A dermal absorption rate of 10% was estimated by the introducer for the notified chemical using calculation based on the physico-chemical properties (Kroes, 2007). Since the notified chemical has a molecular weight > 500 g/mol and has limited water solubility, the value of 10% dermal absorption is considered reasonable (SCCS, 2012).

Daily systemic exposure
Typical daily systemic exposure to the notified chemical when using different types of cosmetic products is shown in the following table, using 10% dermal absorption. For the purposes of exposure assessment via the dermal route, Australian use patterns for various product categories are assumed to be similar to those in Europe (SCCS, 2012; Cadby et al., 2002; ACI, 2010; Loretz et al., 2006). For inhalation exposure estimation, a two-zone approach (Steiling et al., 2014; Rothe et al., 2011; Earnest, Jr, 2009) is used with assumptions of an adult air inhalation rate of 20 m^3/day (enHealth, 2012) and a conservative inhalation fraction of 50%. For calculation purposes, a lifetime average female body weight of 64 kg (enHealth, 2012) is used.

Product type	*Daily systemic exposure (mg/kg bw/day)*
Dermal exposure	
Body lotion	1.2219
Face cream	0.2406
Hand cream	0.3375
Fine fragrances	0.1172
Deodorant (non-spray)	0.2344
Shampoo	0.0163
Conditioner	0.0061
Shower gel	0.0292
Hand wash soap	0.0313

Product type	*Daily systemic exposure (mg/kg bw/day)*
Hair styling products	0.0625
Foundation	0.0797
Facial cleanser	0.0013
Eyeshadow	0.0031
Eyeliner	0.0008
Mascara	0.0039
Make up remover	0.0781
Subtotal	**2.4639**
Oral exposure	
Lipstick	0.0891
Subtotal	**0.0891**
Inhalation exposure	
Hairspray (aerosol)	0.0931
Deodorant (aerosol)	0.1986
Subtotal	**0.2917**
Total	**2.8446**

Based on the calculations, considering the worst case scenario of a consumer exposed simultaneously to all typical cosmetic products containing the notified chemical, the combined internal dose of the notified chemical is estimated at 2.85 mg/kg bw/day. It is acknowledged that exposure to the notified chemical from use of other cosmetic products that are not listed may occur. However, the combination of the conservative exposure parameters and the aggregate exposure pattern from use of the typical products above is considered adequately protective.

6.2. Human Health Effects Assessment

Only limited toxicological information is provided for the notified chemical. The results from toxicological investigations conducted are summarised in the following table. For details of the studies, refer to Appendix B.

Endpoint	***Result and Assessment Conclusion***
Skin irritation – *in vitro* study on reconstructed human epidermis	potentially non-irritating
Eye irritation – *in vitro* study on human corneal epithelium	potentially non-irritating
Skin sensitisation – guinea pig, maximisation test	no evidence of skin sensitisation

Information on structurally similar analogue chemicals was used to assess acute toxicity, skin irritation, eye irritation and repeated dose toxicity of the notified chemical.

Toxicokinetics, Metabolism and Distribution
Based on information derived from analogue chemicals, the notified chemical is expected to be metabolised into fatty acids and glycerol in the gastro-intestinal tract (GIT) (undisclosed reference, 2007). Dermal absorption of the notified chemical is estimated to be 10% given the high molecular weight and limited water solubility (see also Section 6.1.2.)

Acute Toxicity
No data are available on the notified chemical. Based on the available data on the analogue chemicals, the notified chemical is expected to have low acute toxicity following oral or dermal exposure with the median lethal dose (LD50) in rats > 2000 mg/kg bw (undisclosed reference, 2007).

Skin Irritation
According to the results of an *in vitro* assay, the notified chemical is not considered a skin irritant. However, mild skin irritation effects cannot be fully ruled out as a close analogue chemical was reported to be slightly irritating to the skin of rabbits (undisclosed reference, 2007).

Eye Irritation
According to the results of the *in vitro* assay, the notified chemical is not considered an eye irritant. A close analogue chemical is also reported to be non-irritating to the eyes of rabbits (undisclosed reference, 2007).

Skin Sensitisation
Based on the results from a guinea pig maximisation test, the notified chemical is not considered a skin sensitiser when tested at 50% concentration. None of the guinea pigs tested (n = 10) showed allergic skin reactions following exposure to the notified chemical. No skin irritation effects were observed in the study either.

Data on a close analogue chemical support the above conclusion. In a guinea pig maximisation test, the test animals (n = 10) were exposed to the analogue chemical in a two stage induction, followed by a topical challenge two weeks later. At the maximum concentration tested (25%) the analogue did not elicit any sensitising reaction in the animals (undisclosed reference, 2007).

Repeated Dose Toxicity
No data are submitted on the notified chemical. Based on available data on a closely related chemical, the notified chemical is not expected to be harmful following repeated oral exposure.

In a chronic toxicity study, rats were given the closely related chemical at concentrations of 3% or 5% in the diet for 52 weeks. A no observed adverse effect level (NOAEL) of 1200 mg/kg bw/day was established based on the slightly decreased growth at the high concentration with no histopathological abnormalities in the major organs (undisclosed reference, 2001).

Mutagenicity/Genotoxicity
No data were submitted for the notified chemical. Based on the available information on the analogues, the notified chemical is not expected to be genotoxic.

An analogue was tested in a bacterial gene mutation assay (Ames test), an *in vitro* chromosomal aberration test and an *in vivo* bone marrow micronucleus test. In the Ames test, the test substance was found negative in bacteria at concentrations up to 5000 µg/plate with and without metabolic activation. In the chromosomal aberration test, the test substance was found negative in Chinese hamster lung cells at concentrations up to 5000 µg/mL, with and without metabolic activation. In the micronucleus test, the analogue was orally given to mice at doses up to 2000 mg/kg bw in two doses. Apart from a marginal difference, no dose-dependent increase of micronucleus was observed in the study. Overall, the analogue did not show genotoxic potential (undisclosed reference, 2007).

In addition, another two analogues were tested at concentrations up to 10 µg/mL on human fibroblasts for 24 hours. No treatment-related changes to cell proliferation were observed in the study, indicating no effect on DNA synthesis (undisclosed reference, 2007).

Health Hazard Classification

As only limited toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Transport and storage
Dermal, ocular and/or inhalation exposure to products containing ≤ 10% of the notified chemical, or to the neat chemical, may occur in breakage and spill situations for dockside and warehouse workers. Workers are expected to wear PPE including uniforms, gloves, protective glasses and protective shoes to minimise the potential for exposure.

Reformulation
During reformulation processes, workers (including chemists, compounders, store persons and packers) may be exposed to drips, spills and aerosols of the notified chemical at various concentrations up to the neat form. The main route of exposure is expected to be dermal. The notifier anticipates that worker exposure will be limited

through the use of engineering controls such as enclosed systems, automated processes and adequate ventilation. Workers are expected to wear PPE (including protective clothing, gloves and eye protection) to minimise the potential for exposure.

Professional use
Professional workers including beauticians and hairdressers may be exposed to the notified chemical at ≤ 10% concentration in finished cosmetic products. The main route of exposure will be dermal, but ocular and inhalation exposure are also possible. Use of PPE and good hygiene practices are expected to be in place. If PPE is used, exposure of professional workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

Overall, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
Members of the public are expected to be repeatedly exposed to the notified chemical during daily use of cosmetic products containing the notified chemical up to 10% concentration.

The available data indicate that the notified chemical is not expected to be irritating to the skin and eyes and is not a skin sensitiser.

In a worst case scenario for a consumer using simultaneously all types of typical cosmetic products, the internal dose of the notified chemical may reach 2.85 mg/kg bw/day (see Section 6.1.2.). Based on a NOAEL of 1200 mg/kg bw/day derived from a chronic oral toxicity study in rat on a related chemical, the Margin of Exposure (MoE) for the notified chemical is estimated to be 422. An MoE value greater than or equal to 100 is considered acceptable to account for intra- and interspecies differences.

Therefore, based on the information available, the risk to the public associated with the maximum proposed use concentration of the notified chemical at ≤ 10% in 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 either be in the form of finished cosmetic products or blended (reformulated) into cosmetic products. Except in the case of accidental spills and leaks, there is unlikely to be significant release of the notified chemical to the environment from either transport or storage within factory facilities. Blending is expected to occur within a fully enclosed environment. Any accidental spills will be physically contained, mopped up and/or absorbed on an inert material (such as sand or soil) and disposed of to landfill according to local government regulations. Waste containing the notified chemical generated during blending (such as wash waters and residues in empty import containers) will either be released to sewers or disposed of to landfill according to local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used in cosmetic products. After application, the notified chemical is expected to be released to sewer. Direct release into surface water is expected to be minimal.

RELEASE OF CHEMICAL FROM DISPOSAL
It is likely that only a small amount (estimated by the notifier to be < 3% of any formulation) will remain in a product container after final use. Residues of the notified chemical in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate
The submitted biodegradable study indicates that the chemical is readily biodegradable in activated sludge. For details of the study, please see Appendix C. The notified chemical is also unlikely to bioaccumulate based on its surfactant properties.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. It is assumed that 100% of the total import volume of the notified chemical is released to the sewer, release is nationwide over 365 days per year, and there is no removal of the notified chemical during sewage treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	1000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.7	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.4	million
Removal within STP	0	%
Daily effluent production:	4877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River	0.02	µg/L
PEC – Ocean	< 0.01	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 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 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.02 µg/L may potentially result in a soil concentration of approximately 0.13 µg/kg.

As the notified chemical is readily biodegradable it is not expected to accumulate over time in soil.

7.2. Environmental Effects Assessment

Summaries of ecotoxicological investigations conducted on the notified chemical, which were provided by the notifier, are listed in the table below:

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 100 mg/L (OECD TG 203; semi-static)	Not toxic to fish
Daphnia Toxicity	EL50 > 100 mg/L (OECD TG 202; static)	Not toxic to aquatic invertebrates
Algal Toxicity	ErL50 > 100 mg/L (OECD TG 201)	Not toxic to algae
Inhibition of Bacterial Respiration*	EC50 > 1000 mg/L (OECD TG 209)	Not inhibitory to microorganisms at STPs

*The full study report was provided from the notifier in French.

Based on the above acute ecotoxicological endpoints for the notified chemical, it is not expected to be toxic to algae, fish and aquatic invertebrates.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from E(L)50 value of > 1000 mg/L for all trophic levels. Normally a safety factor of 100 could be applied. However, a safety factor of 1000 was used as the studies for the endpoints for all the trophic levels could not be evaluated for reliability, validity or relevance.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Invertebrates)	>100.00 mg/L
Assessment Factor	1000.00
Mitigation Factor	1.00
PNEC	> 100.00 µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q – River	0.02	>100	< 0.01
Q – Ocean	0.00	>100	< 0.01

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified chemical is considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, the notified chemical is not expected to pose an unreasonable risk to the environment.

8. RISK ASSESSMENT FOR EXTENSION APPLICATION

There are no significant changes under the proposed extension to the use. No increase in occupational or public exposure is expected for the extension application. The notified chemical will be introduced in neat form or as finished products at ≤ 10% concentration and used in the same way as in the original assessment. As the total introduction volume will not be increased, the extension of use is not expected to significantly change the amount released to the environment.

Therefore, the circumstances in the extension assessment are not expected to significantly impact on the original human health and environment risk assessment and recommendations.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 58 °C

Method	OECD TG 102 Melting Point/Melting Range
Remarks	
Test Facility	Test Facility A (2011) (Exempt Information)

Boiling Point > 230 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point
Remarks	Decomposition process above 230 °C
Test Facility	Test Facility A (2011) (Exempt Information)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin Irritation – *In Vitro* Reconstructed Human Epidermis Test

TEST SUBSTANCE: Notified chemical

METHOD: EPISKIN TTest-004/02 and TTest-009/01 (No details specified)
Vehicle: None
Remarks – Method: Study summary only was provided. The test item was crushed prior to testing and used undiluted.

Interleukin 1 alpha (IL-1α) release from the test tissues was measured to indicate potential inflammatory response.

RESULTS

	IL-1α Concentration (pg/mL)	*Relative Mean Viability (%)*
Test 1	24.6	98.3
Test 2	0*	100**
Mean ± SD	12.3 ± 17.4	99.2 ± 1.2

* Negative value is regarded as zero.
** Viability > 100 % was regarded as 100%.

Remarks – Results: No study details were provided.

The following acceptability criteria were reported to be met:
- Optical Density (OD) of the negative control ≥ 0.6.
- Relative viability for the positive control (sodium lauryl sulfate) ≤ 35% compared with negative control.

CONCLUSION: The notified chemical was considered to be potentially non-irritating to the skin under the conditions of the test.

TEST FACILITY: Test Facility B (2009) (Exempt Information)

B.2. Eye Irritation – *In Vitro* Cytotoxicity Study on Human Corneal Epithelium

TEST SUBSTANCE: Notified chemical

METHOD: EPISKIN TTest-006/01 (No details specified)
Vehicle: None
Remarks – Method: Study summary only was provided. The test item was crushed prior to testing and used undiluted.

RESULTS

Test Material	*Mean OD_{570} of Duplicate Tissues*	*Relative Mean Viability (%)*
Negative Control	> 0.6	100*
Test Substance	Not provided	100*
Positive Control	Not provided	< 35

* Viability > 100 % was regarded as 100%.

Remarks – Results: No study details were provided.

The following acceptability criteria were reported to be met:
- OD of the negative control ≥ 0.6.
- Relative viability for the positive control (absolute ethanol) ≤ 35% compared with negative control.

CONCLUSION: The notified chemical was considered to be potentially non-irritating to the

eye under the conditions of the test.

TEST FACILITY	Test Facility B (2009) (Exempt Information)

B.3. Skin Sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation – Maximisation test
Species/Strain	Guinea pig/ Pirbright White
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: 5% Topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 10 (5M, 5F) Control Group: 5 (3M, 2F)
Vehicle	Vaseline
Positive Control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 4-aminobenzoic acid ethyl ester (benzocaine).
INDUCTION PHASE	Induction concentration: Intradermal: injections at 5% Topical: occlusive patch at 50% for 48 h
Signs of Irritation	N/A
CHALLENGE PHASE	Topical: occlusive patch at 50% for 24 h
Remarks – Method	Magnusson & Kligman Method

RESULTS

Remarks – Results	No allergic skin reactions (erythema or oedema) were noted in the test animals and no findings were observed in control animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Test Facility C (2001) (Exempt Information)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	
Analytical Monitoring	
Remarks – Method	The test solutions were: (i) test substance; (ii) sodium benzoate (positive control) 100 mg/L; (iii) test substance and sodium benzoate at equal concentrations; (iv) 'abiotic control' consisting of the test substance and mercury (II) chloride. Biodegradation was measured by the percentage oxygen uptake of the chemical oxygen demand.

RESULTS

	Test substance	*Sodium benzoate*	*Test substance and sodium benzoate*	*Test substance and mercury (II) chloride (abiotic control)*
Biodegradation after 14 d (%)	52	89	64	ND
Biodegradation after 28 d (%)	87	91	82	26

Remarks – Results	The 10-day window was not applied to interpret the results as this does not apply to mixtures of structurally similar chemicals. Some of the degradation was by abiotic pathways.
CONCLUSION	The percent degradation of the test substance indicates that it is readily biodegradable under the conditions of the test.
TEST FACILITY	Test Facility A (2010) (Exempt Information)

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