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May 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

9-Octadecenoic acid, 12-hydroxy-, 2-octyldodecyl ester, (*Z*)-

(INCI Name: Octyldodecyl Ricinoleate)

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
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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
LTD/2137	Privity Pty Ltd	9-Octadecenoic acid, 12-hydroxy-, 2-octyldodecyl ester, (*Z*)- (INCI Name: Octyldodecyl Ricinoleate)	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 in the proposed manner, the notified chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the assumed low hazard and reported use pattern, 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 safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols

- 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 as introduced, and during reformulation:
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection if inhalation exposure may occur
  - Protective 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 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(S)
Privity Pty Ltd (ABN: 23 007 887 729)
17-21 Commercial Street
MARLESTONE SA 5033

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Octyldodecyl Ricinoleate (INCI Name)

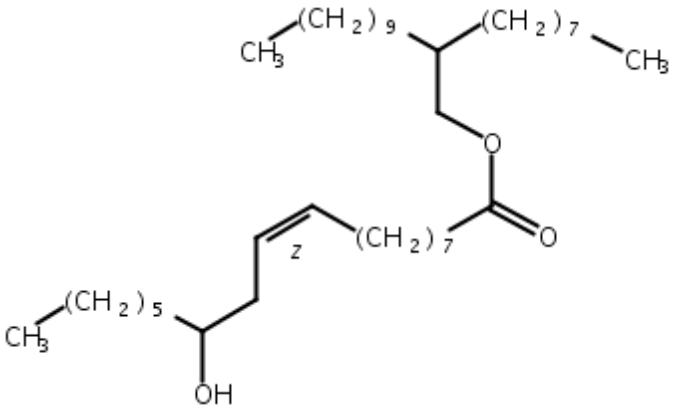
CAS NUMBER
125093-27-8

CHEMICAL NAME
9-Octadecenoic acid, 12-hydroxy-, 2-octyldodecyl ester, (*Z*)-

OTHER NAME(S)
ULTRACAS G-20 GUERBET ESTER

MOLECULAR FORMULA
$C_{38}H_{74}O_3$

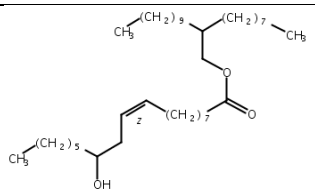
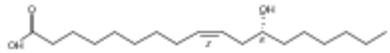
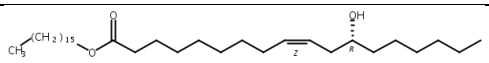
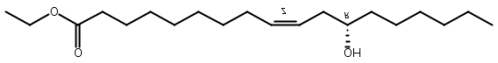
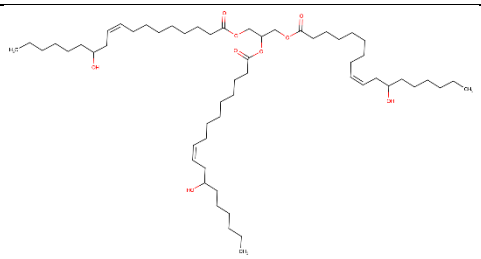
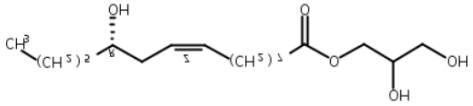
STRUCTURAL FORMULA



MOLECULAR WEIGHT
578.99 g/mol

ANALYTICAL DATA
Reference FTIR spectra was provided.

ANALOGUE CHEMICALS USED IN THE REPORT

Chemical	CAS Name / Common Name	CAS No.	Molecular Formula	Structure	Molecular Weight
Notified chemical	9-Octadecenoic acid, 12-hydroxy-, 2-octyldodecyl ester, (Z)- / Octyldodecyl Ricinoleate1	125093-27-8	$C_{38}H_{74}O_3$		578.99
Analogue 1	9-Octadecenoic acid, 12-hydroxy-, (9*Z*,12*R*)- / Ricinoleic Acid	141-22-0	$C_{18}H_{34}O_3$		298.46
Analogue 2	9-Octadecenoic acid, 12-hydroxy-, hexadecyl ester, (9*Z*,12*R*)- / Cetyl Ricinoleate	10401-55-5	$C_{34}H_{66}O_3$		522.89
Analogue 3	9-Octadecenoic acid, 12-hydroxy-, ethyl ester, (9*Z*,12*R*)- / Ethyl Ricinoleate	55066-53-0	$C_{20}H_{38}O_3$		326.51
Analogue 4	Castor oil	8001-79-4	Unspecified		933.45*
Analogue 5	9-Octadecenoic acid, 12-hydroxy-, 2,3-dihydroxypropyl ester, (9*Z*,12*R*)- / Glyceryl Ricinoleate	141-08-2	$C_{21}H_{40}O_5$		372.54

* The molecular weight is calculated for an idealised fragment with 3 ricinoleic acid molecules bound to the glycerol.

3. COMPOSITION

DEGREE OF PURITY
100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear viscous liquid

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point	251 °C	Calculated (QSAR, 2019)
Boiling Point	599 °C at 101.3 kPa	Calculated (QSAR, 2019)
Relative Density	0.899 kg/m^3 at 25 °C	SDS
Vapour Pressure	2.14×10^{-8} kPa at 25 °C	Calculated (QSAR, 2019)
Water Solubility	Insoluble/2.6×10^{-14} g/L at 20 °C	SDS/Calculated (QSAR, 2019)
Hydrolysis as a Function of pH	t1/2 ~ 10 years	Calculated (QSAR, 2019)
Partition Coefficient (n-octanol/water)	log Pow = 15.7 at 20 °C	Calculated (QSAR, 2019)
Adsorption/Desorption	log K_{oc} = 8.5 at 25 °C	Calculated (QSAR, 2019)
Dissociation Constant	Not determined	Contains no dissociable functions
Flash Point	93.9 °C at 25 kPa	SDS
Autoignition Temperature	Not determined	Not expected to autoignite.
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.

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

Physical Hazard Classification
Based on the submitted estimated 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 as a raw material for reformulation, or imported in end-use cosmetic products at ≤ 10% concentration.

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

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

PORT OF ENTRY
Sydney, Melbourne

IDENTITY OF MANUFACTURER
Lubrizol Advanced Materials Inc.
9911 Brecksville Road
CLEVELAND OHIO USA

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 20 kg plastic bags in cardboard cartons. The formulated end use products containing the notified chemical will be packaged in containers up to 500 mL in size. The imported and end use products containing the notified chemical will be transported within Australia by road.

USE
The notified chemical will be used as a component of leave on and rinse off cosmetic products at ≤ 10% concentration, including aerosol spray products such as deodorant and hair sprays.

OPERATION DESCRIPTION

Reformulation
The reformulation procedure will likely vary depending on the nature of the formulated products, and may involve both automated systems and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation, followed by automated filling (using sealed delivery systems) of the reformulated products into containers of various sizes.

End-use
The finished cosmetic products containing the notified chemical at ≤ 10% concentration will be used by consumers and professionals such as beauticians and hairdressers. Depending on the nature of the product, application of 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)*
Transport and Storage	4	12
Professional Compounder	8	12
Chemist	3	12
Packer (Dispensing and Capping)	8	12
End Users	8	365

EXPOSURE DETAILS

Transport and storage
Transport, storage and warehouse workers may come into contact with the notified chemical only in the event of accidental rupture of containers.

Reformulation
During reformulation dermal and ocular exposure of workers to the notified chemical may occur during handling the notified chemical, during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. It is expected that exposure will be minimised through the use of enclosed systems, and workers wearing personal protective equipment (PPE) such as protective clothing, eye protection and impervious gloves, as stated by the notifier. Inhalation exposure is not expected (Unless aerosols are generated) given the low vapour pressure of the notified chemical.

Professional end-users
Exposure to the notified chemical in end-use products at ≤ 10% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. hairdressers and workers in beauty salons). 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 the products containing the notified chemical (see section 6.1.2).

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical at up to 10% concentration through the use of cosmetic products. The main route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human Health Effects Assessment

The result from a skin sensitisation study conducted on the notified chemical is summarised in the following table. For details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Skin sensitisation – HRIPT (100%)	no evidence of sensitisation

Toxicokinetics, Metabolism and Distribution

No toxicokinetic data was provided for the notified chemical. For dermal absorption, chemicals with molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Water solubility below 1 mg/L and log P values greater than 4 are also expected to limit dermal absorption (ECHA, 2017). Based on the notified chemical's molecular weight of 578.99 g/mol, estimated log Pow 15.73 at 20 °C, and estimated water solubility of 2.6×10^{-14} g/L at 20 °C, the dermal absorption is expected to be low. Castor oil is readily absorbed through the gastrointestinal tract (CIR, 2007).

Acute Toxicity

No data are available on the acute toxicity of the notified chemical itself. Acute toxicity data are available on the analogue chemicals: for acute oral toxicity LD50 of > 2,000 and > 5,000 mg/kg bw for cetyl ricinoleate and ethyl ricinoleate, respectively (CIR, 2007), and > 25 mL/kg bw (> 25,700 g/kg bw) for glyceryl ricinoleate (CIR, 1988). The acute dermal toxicity LD50 for ethyl ricinoleate was reported as > 5,000 mg/kg bw (CIR, 2007). Therefore, the notified chemical is expected to have a low acute toxicity via oral or dermal exposure. There was no data available on the acute inhalation toxicity of the analogues.

Irritation and Sensitisation

No eye irritation data were available for the notified chemical. Castor oil was only slightly irritating to rabbit eyes in a number of studies (CIR, 2007). In humans castor oil produced mild and transient discomfort and minor epithelial changes following repeated exposure over 15 days in one study and in another study with 100 patients, castor oil produced corneal epithelial cell death and continuity breaks in the epithelium (CIR, 2007).

Castor oil was non- to mildly irritating to skin in a number of studies on rabbits, guinea pigs, rats and miniature swine (CIR, 2007). Castor oil was also not a significant skin irritant in human tests (CIR, 2007). Ricinoleic acid is reported to be non-irritating to the skin of rabbits and in mice and exhibited well defined erythema in another rabbit study (CIR, 2007). Cetyl was not a skin irritant in a study in rabbits (CIR, 2007). The notified chemical (100% concentration) applied under an occlusive dressing for 48 hours produced mild erythema in 4/57 subjects during the induction phase of an HRIPT study. No signs of irritation or skin reactions were seen at challenge, the notified chemical is not considered to be a skin irritant or a skin sensitiser.

Zinc ricinoleate (the zinc salt of analogue 1) at a concentration of 50% produced no evidence of skin sensitisation in guinea pigs (CIR, 2007). Ethyl ricinoleate at 20% concentration showed no irritation or sensitisation effects in a maximisation (occlusion) test with 32 male volunteers (CIR, 2007). In 49 patients with contact dermatitis, a patch-test (48 hours Finn chambers) with castor oil, none had a positive skin reactions and in a different study 1/76 dermatitis patients patch-tested with castor oil had a positive reaction (CIR, 2007).

Based on the analogue data, the notified chemical is not expected to be a skin or an eye irritant.

Repeated Dose Toxicity

No data are available on the notified chemical. In two chronic toxicity studies, in rats and mice administered with castor oil at up to 10% concentration for 13 weeks in the diet the no observed adverse effect level (NOAEL) was established as 7,500 and 5,000 mg/kg bw/day for mice and rats, respectively (Burdock *et al.*, 2006).

Based on the available data the notified chemical is not expected to cause harmful systemic effects following repeated exposure.

Mutagenicity/Genotoxicity
No data are available on the notified chemical. Castor oil at up to 10,000 µg/plate was non-mutagenic using *Salmonella typhimurium* strains with or without metabolic activation (CIR, 2007). Castor oil also did not induce sister chromatid exchanges in Chinese hamster ovary cells either with or without metabolic activation (CIR, 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
The notified chemical is expected to be of low acute and repeated dose systemic toxicity. Slight skin and eye irritation cannot be rules out, based on analogue data.

Reformulation
During reformulation, dermal, ocular and inhalation exposure of workers to the notified chemical may occur. It is stated by the notifier that engineering controls such as enclosed system and with exhaust hoods will be implemented where possible, and appropriate PPE (including a certified respirator with an organic vapour cartridge and P95 particulate filter if ventilation is inadequate) will be used to limit exposure to workers.

Therefore, under the occupational settings described, the risk to the health of workers from use of the notified chemical 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 may be exposed to the notified chemical at concentrations up to 10%. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the risk to such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various products containing the notified chemical.

6.3.2. Public Health
Cosmetic products containing the notified chemical at ≤ 10% concentration will be available to the public. The main route of exposure is expected to be dermal and inhalation (if aerosol products are used), with some potential for accidental ocular or oral exposure.

The notified chemical is expected to be of low acute and repeated systemic toxicity, due to expected low dermal absorption. Although it may produce mild skin and eye irritation effects, at the proposed use concentration of 10% irritation effects are not expected.

Therefore, based on the information available, the risk to the public associated with use of the notified chemical at ≤ 10% concentration 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 not be manufactured in Australia. The notified chemical will be imported as a raw material and blended into finished cosmetic products or as a component of finished cosmetic products. Release of the notified chemical is expected to be < 1% and will be from spills during the transport, storage and product reformulation and washing of equipment after reformulation. Accidental spills and equipment washings will be collected for disposal to sewer or to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Most of the notified chemical will primarily be rinsed into the sewer system as a part of its use in cosmetic products.

RELEASE OF CHEMICAL FROM DISPOSAL

A small proportion (approximately 3%) of the notified chemical may remain in end-use containers once the cosmetic products are used up. Wastes and residue 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

No environmental fate data were submitted. Most of the notified chemical is expected to enter the sewer system before potential release to surface waters on a nationwide basis. A proportion of the notified chemical may be partition to air. The half-life of the notified chemical in air is calculated to be < 2 h, based on reactions with hydroxyl radicals (US EPA, 2012; calculated using AOPWIN v1.92). Therefore, the notified chemical is not expected to persist in the air compartment.

The notified chemical is expected to highly sorb to sludge at STPs based on its low water solubility and high, calculated partition coefficient (log P_{ow} = 15.7). Therefore, the notified chemical is expected to be removed effectively at STPs through biodegradation (US EPA, 2012; calculated using BIOWIN v4.10) and adsorption to sludge, and only a small portion of the notified chemical may be released to surface waters. A proportion of the notified chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. The notified chemical residues in landfill and soils are expected to have low mobility based on its calculated soil adsorption coefficient (log K_{oc} = 8.5). The notified chemical is not expected to be bioaccumulative based on based on the modelled bioconcentration factor (BCF) of 3.16 and its biodegradability. In the aquatic and soil compartments, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in most of the notified chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 100% release of the notified chemical into sewer systems nationwide over 365 days per annum. The extent to which the notified chemical is removed from the effluent in STP processes based on the properties of the notified chemical has not been considered for this scenario, and therefore no removal of the notified chemical during sewage treatment processes, is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	1000.00	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	Million
Removal within STP	0	%
Daily effluent production:	4,872	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	0.56	µg/L
PEC – Ocean:	0.06	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 0.562 µg/L may potentially result in a soil concentration of approximately 3.745 µg/kg. Since the notified chemical is degradable, no accumulation is expected.

7.2. Environmental Effects Assessment

No ecotoxicity study was conducted on the notified chemical, but the notifier provided the modelling results of the aquatic toxicity of the notified chemical. The modelling results indicate that the notified chemical is not harmful to aquatic life in environmental water at the saturation limit of its water solubility (QSAR, 2019).

The modelling results are considered reliable to provide general indications of the likely environmental effects of the notified chemical. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified chemical to aquatic life under the *Globally Harmonised System for the Classification and Labelling of Chemicals* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A PNEC could not be calculated but the notified chemical is predicted to have no effect at the saturation limit of its water solubility.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified chemical has not been calculated as the notified chemical is predicted to have no effect on aquatic organisms up to its water solubility limit or at saturation. Therefore, based on the assumed low hazard, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin Sensitisation – Human Volunteers

TEST SUBSTANCE	Notified chemical at 100%
METHOD	Repeated insult patch test with challenge. Modified Draize Assay
Study Design	Induction procedure: 0.025 mL of the test material was applied three times a week for a total of 10 applications. A reading of the patch sites were taken at the end of each 48 hours period (or 72 hour period on the weekend). Rest period: 12 days Challenge procedure: Patches were applied 12 days after the tenth induction patch and remained in place for 48 hours. Challenge results were scored 48 and 96 hours after patch application. .
Study Group	46 F, 11 M; age range 21 to 70+ years
Vehicle	The test substance was administered as supplied
Remarks – Method	Sensitisation potential was assessed according to a modified Draize test (Occlusive test). The test substance was spread on the skin sites (on the scapular back) by means of an 8 mm Finn Chamber. 57 of 59 subjects completed the study. Individual results of skin reactions for each of the subjects were not included in the study report.
RESULTS	
Remarks – Results	Erythema was observed in 4 subjects during induction phase, there was no oedema observed. There were no skin reactions noted in the challenge phase.
CONCLUSION	The notified chemical was non-sensitising under the conditions of the test.
TEST FACILITY	(IRSI, 1998)

BIBLIOGRAPHY

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