File No.: LTD/2114

January 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Oils, Persicaria odorata

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:

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Director
NICNAS

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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/2114	International Flavours & Fragrances (Australia) Pty Ltd	Oils, Persicaria odorata	ND*	≤ 1 tonne per annum	Fragrance 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 maximum import volume of one tonne per annum, 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
  - 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:
  - Avoid contact with skin and eyes
  - Avoid inhaling aerosols or mists

- 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
  - Safety glasses or goggles
  - Protective clothing
  - Respiratory protection if aerosols or mists are expected to be generated

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 0.1% in cosmetic and household products;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from fragrance 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 and a product containing 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)
International Flavours and Fragrances (Australia) Pty Ltd (ABN: 77 004 269 658)
310 Frankston-Dandenong Road
DANDENONG VIC 3175

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 physical and chemical properties except for vapour pressure and flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US, EU (REACH)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polygonum oil

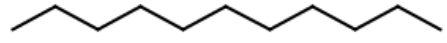
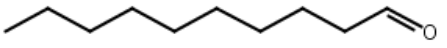
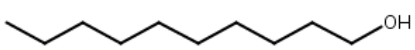
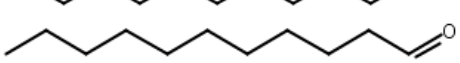
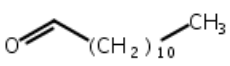
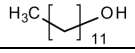
CAS NUMBER
444085-42-1

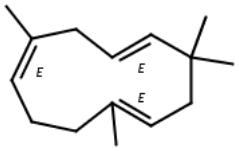
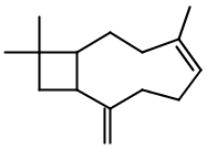
CHEMICAL NAME
Oils, Persicaria odorata

OTHER NAME(S)
Polygonum odoratum; Polygonium odoratum; Polygonum oil LMR

MOLECULAR FORMULA
Unspecified (UVCB)

STRUCTURAL FORMULA
The structure for the notified chemical is unspecified. Based on the GC results, individual components for the notified chemical were characterised (accounting for 97.1%) and the structures for these components are presented in the below table.

GC results for the notified chemical			
Chemical name	CAS number	Area %	Structure
Undecane	1120-21-4	2.8	
Decanal	112-31-2	12.2	
1-Decanol	112-30-1	4.4	
Undecanal	112-44-7	1.4	
Dodecanal	112-54-9	62.9	
1-Dodecanol	112-53-8	7.8	

		GC results for the notified chemical	
1,4,8-Cycloundecatriene, 2,6,6,9-tetramethyl-, (1*E*,4*E*,8*E*)-	6753-98-6	2.6	
Bicyclo[7.2.0]undec-4-ene, 4,11,11-trimethyl-8-methylene-	13877-93-5	3.0	
Unknown		2.5	

MOLECULAR WEIGHT
< 500 g/mol (UVCB components identified)

ANALYTICAL DATA
Reference NMR, IR, UV/Vis and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
UVCB (8 components were identified in one batch of GC results, accounting for 97.1% of total mass)

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid with some crystals.

Property	***Value***	***Data Source/Justification***
Melting Point	< -100-44.5 °C	Information provided by the notifier on the main components
Boiling Point	130-273 °C	Information provided by the notifier on the main components
Density	843-883 kg/m^3	SDS
Vapour Pressure	7.97 × 10^{-3} kPa at 24 °C	Measured
Water Solubility	0.004-43.5 mg/L	Information provided by the notifier on the main components
Hydrolysis as a Function of pH	Not determined	Contain no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow = 3.8-6.3	Information provided by the notifier on the main components
Adsorption/Desorption	log Koc = 2.6-5.5	Information provided by the notifier on the main components
Dissociation Constant	Not determined	Contain no dissociable functionalities
Flash Point	108 °C at 101.3 kPa	Measured
Autoignition Temperature	-	Not tested
Explosive Properties	Predicted negative	The main components contain no functional groups that would imply explosive properties.
Oxidising Properties	Predicted negative	The main components contain no functional groups that would imply oxidising properties.

DISCUSSION OF PROPERTIES
For 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.

The notified chemical has a flash point of 108 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid if the chemical has a fire point below the boiling point.

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 and will not be imported into Australia in neat form. It will be imported into Australia as a component of finished fragrance oil products. The fragrance oil products will contain the notified chemical at ≤ 1% concentration and will be reformulated locally to produce household and cosmetic products.

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
Melbourne

IDENTITY OF RECIPIENTS
International Flavours and Fragrances (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING
The finished fragrance oil products containing the notified chemical (at ≤ 1% concentration) will be imported in 208 L polypropylene-lined steel drums. The imported products containing the notified chemical will be transported by road to the International Flavours and Fragrances (IFF) facility in Victoria and then distributed to reformulation sites. The end-use products will be packaged in containers suitable for retail sale.

USE
The notified chemical will be used as a fragrance ingredient and incorporated into a variety of cosmetic and household products at ≤ 0.1% concentration.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. No reformulation or repackaging of products containing the notified chemical will occur at the IFF facility. The imported finished fragrance oils containing the notified chemical (at ≤ 1% concentration) will be stored at the IFF facility until they are sold and distributed to customer facilities for reformulation into end-use cosmetic and household products.

Reformulation
At the customer reformulation sites, procedures for incorporating fragrance oil products containing the notified chemical into end-use products will likely vary depending on the nature of the formulated products and may involve both automated and manual transfer steps. In general, it is expected that the products containing the notified chemical will be weighed and added to the mixing tank where mixing with additional additives will occur to form finished cosmetic and household products. Subsequently, automated filling of the reformulated products into containers of various sizes will occur. The blending and filling operations are expected to be typically automated with enclosed systems and adequate ventilation. During the reformation process, samples of products containing the notified chemical will be taken for quality control purposes.

End use

Cosmetic products

The finished cosmetic products containing the notified chemical at ≤ 0.1% concentration will be used by consumers and professionals such as beauticians and hairdressers. Depending on the nature of the products, applications may be by hand, spray or through the use of applicators.

Household products

Household products containing the notified chemical at ≤ 0.1% concentration may be used by consumers and professional workers such as cleaners. The products may be used in either closed systems with episodes of controlled procedures, for instance automatic washing machine cycles, or open manual processes including spraying, brushing, dipping, wiping and rinsing.

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	Incidental	Incidental
Compounding	4	250
Drum handling	1	250
Drum cleaning	2	200
Maintenance	2	250
Quality control	1	250
Professional users	8	250

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified chemical as a component of finished fragrance oils (at ≤ 1% concentration), only in the unlikely event of an accidental breach of import containers.

Reformulation

During reformulation, dermal, ocular and inhalation exposure of workers to the notified chemical (at ≤ 1% concentration) may occur during weighing, transfer, blending, quality control analysis, cleaning and maintenance. The use of engineering controls including local exhaust ventilation and enclosed systems, and the use of personal protective equipment (PPE) such as coveralls, goggles, impervious gloves and appropriate respiratory protection by workers are expected to minimise exposure to the notified chemical.

End-use

Exposure to the notified chemical in end-use products at ≤ 0.1% concentration may occur in professions where the services provided involve the application of cosmetic products to clients (i.e., hair and beauty salons) or where the cleaning products are used in the cleaning industry. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible. Such professionals may use PPE to minimise repeated exposure and good hygiene practices are expected to be in place. If appropriate PPE is used, exposure of such workers to the notified chemical is expected to be similar or to a lesser extent of that experienced by consumers using the same products.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical at ≤ 0.1% concentration through the use of a wide range of cosmetic and household products. The main route of exposure will be dermal, while ocular and inhalation exposures (e.g. through the use of spray products) are also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Skin sensitisation – HRIPT (0.1%)	no evidence of sensitisation

Toxicokinetics
No information on the toxicokinetics of the notified chemical was provided. For dermal absorption, molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Substances with water solubilities below 1 mg/L are likely to have low dermal uptake while absorption low to moderate if water solubility is between 1-100 mg/L (ECHA, 2017). Dermal absorption is also expected to be more rapid for those substances with lop P values between 1 and 4, while for substances with log P values above 4 the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis (ECHA, 2017). Given the moderately low molecular weight of the notified chemical (molecular weight range for known constituents is < 500 g/mol), the water solubility of 0.004-43.5 mg/L and partition coefficient of 3.8-6.3 for the main components absorption across the skin may occur.

Acute Toxicity
The notified chemical is of low acute oral toxicity based on a study conducted in rats.

No acute dermal or inhalation toxicity studies on the notified chemical were provided.

Irritation and Sensitisation
No skin or eye irritation studies on the notified chemical were provided.

In a human repeated insult patch test (HRIPT), the notified chemical at 0.1% induction concentrations in ethanol:diethyl phthalate (3:1) did not elicit a positive irritation or sensitisation response in 100 individuals.

The notified chemical contains aldehydes, including decanal (CAS No. 112-31-2), undecanal (CAS No. 112-44-7) and dodecanal (CAS No. 112-54-9) (accounting for 76.5% of notified chemical), which are considered as structural alerts for corrosion/skin irritation and sensitisation (Gerner *et al.*, 2004, Hulzebos *et al.*, 2005 and Barratt *et al.*, 1994). European Food Safety Authority (EFSA)'s Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considered dodecanal (CAS No. 112-54-9) as irritating to skin, eyes and respiratory tract and sensitising to skin (EFSA, 2013).

Repeated Dose Toxicity
No repeated dose toxicity data on the notified chemical was provided.

Undecane which makes up 2.8% of the notified chemical has a NOEL of 100 mg/kg bw/day for systemic effects in parental animals in a reproductive/developmental toxicity study (Amoruso *et al*., 2008). 1-Decanol, which makes up 4.4% of the notified chemical, produced no adverse effects in pregnant rats or their offspring when administered via inhalation for 7 h/day on gestation days 1-19 at the maximum obtainable vapour concentration of 100 mg/m^3 (Nelson *et al*., 1990). 1-Dodecanol, which makes up 7.8% of the notified chemical was of low toxicity in rats dosed at up to 2,000 mg/kg/bw/day for 37 days (OECD, 1995).

No information on the repeated dose toxicity of the aldehyde components of the notified chemical was available. However, there is repeated dose toxicity data on two similar aliphatic aldehydes, namely acetaldehyde and hexanal where in 28 day oral studies they were found to have no observed effect levels (NOEL) of 125 and > 125 mg/kg bw/day respectively (WHO, 1998). The main component of the notified chemical, dodecanal (CAS No. 112-54-9), is permitted as a flavouring substance in food (FDA, 2019).

Based on the above information on components and analogues of the notified chemical it is expected to have low to moderate systemic toxicity.

Mutagenicity/Genotoxicity
No studies on the mutagenicity/genotoxicity of the notified chemical were provided. The notified chemical contains aldehydes, including decanal (CAS No. 112-31-2), undecanal (CAS No. 112-44-7) and dodecanal (CAS No. 112-54-9) (accounting for 76.5% of notified chemical), which are considered as structural alerts for carcinogenicity (Benigni *et al.,* 2008). Decanal was positive in a rec assay (using H17 and M45) on *Bacillus subtilis*, but negative in a second rec assay on *E. coli* (using WP2, uvrA), and negative in chromosomal aberration (using Chinese hamster fibroblast cells) and Ames tests (using *S. typhmiurium* TA92, TA1535, TA100, TA1537, TA94 and TA98) (WHO, 1998). Undecanal was also non-mutagenic in an Ames test (WHO, 1998). The WHO

(1998) report noted that positive results in *in vitro* genotoxicity assays for aliphatic aldehydes is not surprising due to their reactivity. However, the *in vivo* conditions where aldehydes are expected to have a short plasma half-life before being oxidised to the corresponding acid and metabolised in fatty acid pathways are difficult to replicate in *in vitro* studies (WHO, 1998). Based on results of genotoxicity studies for decanal and undecanal, which while only making up 13.6% of the notified chemical are good analogues for dodecanal which contributes a further 62.9%, the notified chemical is not expected to be genotoxic.

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.

The notifier has classified the notified chemical as a Category 1B Skin Sensitiser: H317 – May cause an allergic skin reaction mainly based on the skin sensitising potential for dodecanal (CAS No.112-54-9) (accounting for 62.9% of notified chemical).

6.3. Human Health Risk Characterisation
The notified chemical was classified as a skin sensitiser by the notifier as it contains potentially sensitising components at > 60%. The notified chemical also contains structural alerts for corrosion/irritation. However, at the proposed maximum end use concentration of 0.1% the notified chemical showed no evidence of sensitisation in 100 subjects (HRIPT). Based on its low molecular weight, the notified chemical may be absorbed across biological membranes; however, the systemic toxicity of the notified chemical is expected to be low to moderate based on components and analogues of the notified chemical.

6.3.1. Occupational Health and Safety
Reformulation
Workers may experience dermal, ocular and perhaps inhalation exposure to the notified chemical at ≤ 1% concentration during reformulation. The use of local ventilation, enclosed/automated processes and PPE by workers (i.e., protective clothing, goggles, impervious gloves and respiratory protection, if inhalation exposure may occur) are expected to minimise the potential for exposure.

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

End-use
Cleaners and beauty care professionals will handle the notified chemical at up to 0.1% concentration, similar to public use. Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. Therefore, the risk to workers who use products containing the notified chemical is expected to be of a similar or lesser extent than consumers who use such products on a regular basis. For details of the public health risk assessment see section 6.3.2 below.

6.3.2. Public Health
Members of the public may experience repeated exposure to the notified chemical through the use of cosmetic and household products containing the notified chemical at up to 0.1% concentration.

Irritation and Sensitisation
The notified chemical is potentially irritating/corrosive and a skin sensitiser. Significant irritation or sensitisation effects are not expected from the use of products containing the notified chemical at the proposed low use concentration (up to 0.1%) in cosmetic and household products, based on no skin effects in an HRIPT study at the same concentration.

Systemic toxicity
The repeated dose toxicity effects of the notified chemical are expected to be low to moderate. Systemic exposure is expected to be limited by the low concentration of the notified chemical (up to 0.1%) in end use products.

Therefore, based on the information available, the risk to the public associated with use of the notified chemical at up to 0.1% concentration in cosmetic and household 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 as a component of fragrance oils for reformulation into cosmetic and household products. In general, reformulation processes are expected to involve automated blending operation in an enclosed environment, followed by automated filling of finished products into end-use containers. Wastewater generated from reformulation equipment cleaning is expected to be treated on-site before release to sewer or disposed of, in accordance with local government regulations. Empty import containers will be either recycled or disposed of through an approved waste management facility. Accidental spills or leaks of the notified chemical is expected to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewers across Australia as a result of its use in cosmetic and household products, which are washed off hair and skin of consumers as well as from cleaning activities.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified chemical in empty end-use containers, estimated by the notifier to account for up to 1% of the total import volume, are either recycled or disposed of to landfill, in accordance with local government regulations.

7.1.2. Environmental Fate

The majority of the notified chemical is expected to be released to sewers, and then to sewage treatment plants (STPs). Information provided by the notifier indicate that all the main components of the notified chemical are biodegradable. Therefore, the notified chemical is expected to be removed effectively through biodegradation process at STPs before potential release to surface waters. A very small proportion of the notified chemical may adsorb to sludge in STPs. The waste sludge containing the notified chemical will be sent to landfill for disposal or spread over agricultural land. A minor amount of the notified chemical may also be disposed of to landfill as collected spills and empty container residues. The notified chemical is expected to have low mobility in soil based on its log Koc. In landfill, soil, sludge and water, the notified chemical is expected to undergo degradation by biotic and abiotic processes, eventually forming 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	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1	
Dilution Factor – Ocean	10	
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 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 0.56 µg/L may potentially result in a soil concentration of approximately 3.74 µg/kg. Due to the notified chemical's biodegradability, annual accumulation is not expected.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified chemical.

7.2.1. Predicted No-Effect Concentration (PNEC)

The Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicity data were submitted for the notified chemical.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated as no ecotoxicity data were submitted for the notified chemical. On the basis of the maximum import volume of one tonne per annum, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure $7.97 \pm 0.03 \times 10^{-3}$ kPa at 24 °C

Method	Equivalent to OECD TG 104 Vapour Pressure
Remarks	It was determined by dynamic headspace gas chromatography.
Test Facility	International Flavors & Fragrances (IFF) (2019)

Flash Point 108 ± 1 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	A Grabner Miniflash FLP closed cup method was used.
Test Facility	International Flavors & Fragrances (IFF) (2019)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (1996)
Species/Strain	Rat/Sprague-Dawley
Vehicle	Corn oil
Remarks – Method	No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 per sex	2,000	0/6

Discriminating Dose	> 2000 mg/kg bw
Signs of Toxicity	Hypoactivity (1/6 animals), piloerection and dyspnoea (all the animals) were noted on day 1 only.
Effects in Organs	No abnormalities were observed at necroscopy.
Remarks – Results	All animals showed expected body weight gains during the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	CIT (2002)

B.2. Skin Sensitisation – Human Volunteers

TEST SUBSTANCE	Notified chemical at 0.1% concentration in ethanol:diethyl phthalate (3:1)
METHOD	Repeated insult patch test with challenge
Study Design	Induction procedure: patches containing the test substance (0.1% of the notified chemical) were applied 3 times per week (Monday, Wednesday and Friday) for a total of 9 applications during the induction period. Patches were removed by the subjects after 24 hours and graded by technicians after an additional 24 hours (or 48 hours for patches applied on Friday). Rest period: 14 days Challenge procedure: patches containing the notified chemical at 0.1 concentration were applied to a naïve site and were removed by technicians 24 hours after application. The sites were scored 24, 48 and 72 hours after application.
Study Group	96 F, 16 M; age range 19-70 years
Vehicle	None
Remarks – Method	Occluded.
RESULTS	
Remarks – Results	One hundred subjects completed the study. Twelve subjects discontinued with the study for reasons unrelated to the test substance. No other adverse responses were noted at induction and challenge with the test substance at 0.1% concentration.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	CRL (2002)

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