File No.: LTD/2142

July 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Santalum austrocaledonicum, ext.

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019 (the IC Act) and Industrial Chemicals (General) Rules 2019 (the IC Rules) by following the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act) and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules).* The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) 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 AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2142	International Flavours and Fragrances (Australia) Pty Ltd	Santalum austrocaledonicum, ext.	Yes	≤ 1 tonne per annum	Fragrance ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard Classification	*Hazard Statement*
Skin Irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1B)	H317 – May cause an allergic skin reaction

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

Hazard Classification	*Hazard Statement*
Acute (Category 1)	H400 – Very toxic to aquatic life

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

When used in the proposed manner, the assessed chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the PEC/PNEC ratio, the assessed chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The assessed chemical should be classified as follows:
  - Skin irritation (Category 2): H315 – Causes skin irritation
  - Skin Sensitisation (Category 1B): H317 – May cause an allergic skin reaction

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical during reformulation:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation and/or appropriate extraction systems, where possible

- 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 assessed chemical during reformulation:
  - Avoid contact with skin
  - Avoid inhalation of 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 assessed chemical during reformulation:
  - Impervious gloves
  - Protective clothing
  - Respiratory protection if aerosol 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 assessed 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.

Health Surveillance

- As the assessed chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

Storage

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

Emergency procedures

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

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC Act the applicant of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the importation volume exceeds one tonne per annum assessed chemical;
- the final use concentration of the assessed chemical exceeds 0.1% in cosmetic and household products;
- the function or use of the chemical has changed from a fragrance ingredient, or is likely to change significantly;
- the chemical has begun to be manufactured in Australia; and
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of a product containing the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
International Flavours and Fragrances (Australia) Pty Ltd (ABN: 77 004 269 658)
310 Frankston-Dandenong Road
DANDENONG VIC 3175

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

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
No details are taken to be protected information.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for water solubility, partition co-efficient, absorption/desorption, dissociation constant, hydrolysis as a function of pH, explosive properties and oxidising properties.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
EU (1990)
Philippines (2020)
Taiwan (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sandalwood new caledonia

CAS NUMBER
91845-48-6

CHEMICAL NAME
Santalum austrocaledonicum, ext.

OTHER NAME(S)
Sandalwood oil new caledonia
Sandalwood austrocaledonien oil
Santal oleoresine DM
Santal austrocaledonien DM

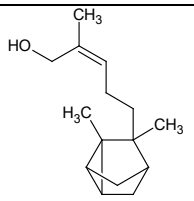
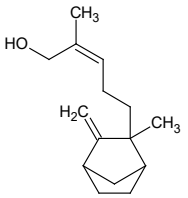
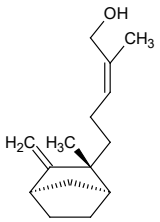
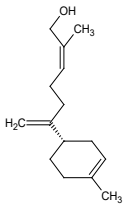
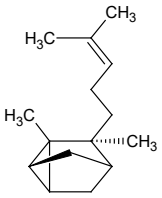
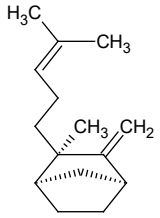
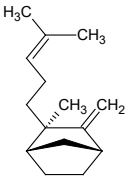
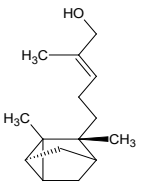
MOLECULAR FORMULA
Unspecified (UVCB)

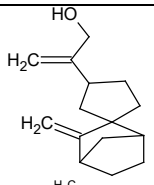
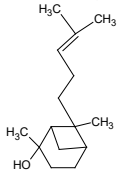
STRUCTURAL FORMULA
The definition of the assessed chemical is the following:

Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Santalum austrocaledonicum, Santalaceae plant.

The applicant provided the following structures for the components of the assessed chemical:

GC results for the assessed chemical			
Chemical name	CAS number	Typical concentration (%)	Structure

GC results for the assessed chemical			
2-Penten-1-ol, 5-[(1R,3R,6S)-2,3-dimethyltricyclo[2.2.1.0^{2,6}]hept-3-yl]-2-methyl-, (2Z)-	115-71-9	49.19	
2-Penten-1-ol, 2-methyl-5-[(1S,2R,4R)-2-methyl-3-methylenebicyclo[2.2.1]hept-2-yl]-, (2Z)-	77-42-9	1.01	
2-Penten-1-ol, 2-methyl-5-[(1R,2S,4S)-2-methyl-3-methylenebicyclo[2.2.1]hept-2-yl]-, (2Z)-rel-	27542-07-0	21.44	
2,6-Heptadien-1-ol, 2-methyl-6-[(1S)-4-methyl-3-cyclohexen-1-yl]-, (2Z)-	10067-28-4	3.03	
Tricyclo[2.2.1.02,6]heptane, 1,7-dimethyl-7-(4-methyl-3-penten-1-yl)-, (2R,6S,7S)-	512-61-8	1.34	
Bicyclo[2.2.1]heptane, 2-methyl-3-methylene-2-(4-methyl-3-penten-1-yl)-, (1R,2R,4S)-	25532-78-9	1.06	
Bicyclo[2.2.1]heptane, 2-methyl-3-methylene-2-(4-methyl-3-penten-1-yl)-, (1S,2R,4R)-	511-59-1	1.05	
2-Penten-1-ol, 5-[(1R,3R,6S)-2,3-dimethyltricyclo[2.2.1.02,6]hept-3-yl]-2-methyl-, (2E)-	14490-17-6	3.66	

GC results for the assessed chemical			
Spiro[bicyclo[2.2.1]heptane-2,1'-cyclopentane]-3'-ethanol, β,3-bis(methylene)-	78220-48-1	1.13	
2,6-dimethyl-6-(4-methylpent-3-en-1-yl)bicyclo[3.1.1]heptan-2-ol	unassigned	6.65	
Unknown	—	10.44	—

MOLECULAR WEIGHT
204 — 222 g/mol (from the UVCB components identified)

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

3. COMPOSITION

DEGREE OF PURITY
100% (UVCB)

HAZARDOUS IMPURITIES
None identified

NON HAZARDOUS IMPURITIES (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear colourless to pale yellow liquid

Property	***Value***	***Data Source/Justification***
Freezing Point	< -20 °C	Measured
Boiling Point	Decomposes prior to boiling	Measured
Density	976.3 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.49 x 10^{-1} kPa at 20 °C 4.27 x 10^{-1} kPa at 25 °C	Measured
Water Solubility	0.0256 – 6.414 mg/L	Estimated using EPI Suite (USEPA, 2012)
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse in water
Partition Coefficient (n-octanol/water)	log Pow = 4.96 – 6.64	Estimated using EPI Suite (USEPA, 2012)
Adsorption/Desorption	log K_{oc} = 3.12 – 4.27	Estimated using EPI Suite (USEPA, 2012)
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Flash Point	145.5 °C at 101.3 kPa	Measured
Flammability	Combustible liquid	Based on the measured flash point
Autoignition Temperature	255 °C	Measured
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties

Property	*Value*	*Data Source/Justification*
Oxidising Properties	Predicted negative	Contains 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 assessed 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 assessed 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 assessed chemical has a flash point of 145.5 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed 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 ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will not be manufactured in Australia. It will be imported into Australia as a component of fragrance oil formulations at ≤ 1% concentration for reformulation into cosmetic and household products.

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

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

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The assessed chemical will be imported as a component of fragrance oil formulations at ≤ 1% concentration in 208 L polypropylene lined steel drums. Within Australia the drums will be transported mainly by road to the warehouse for storage and later distributed to the formulators by road for reformulation. Finished consumer products containing the assessed chemical will be transported primarily by road to retail stores in packages suitable for retail sale.

USE
The assessed chemical will be used as a fragrance ingredient in cosmetics and household products at final use concentrations of ≤ 0.1%.

OPERATION DESCRIPTION

Reformulation
Reformulation of the assessed chemical into finished consumer goods may vary depending on the type of product and may involve both automated and manual transfer steps. Typically, reformulation processes may incorporate blending operations that are highly automated and occur in a fully enclosed/contained environment, followed by automated filling of the reformulated end-use products into containers of various sizes.

End-use
End-use products containing the assessed chemical at ≤ 0.1% concentration will be used by consumers and professionals such as hairdressers, beauticians or cleaners. Depending on the nature of the product, these could be applied in a number of ways, such as by hand, using an applicator or sprayed.

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 warehouse	None	Incidental
Mixer	4	250
Drum handling	1	250
Drum cleaning/washing	2	250
Maintenance	2	250
Quality control	1	250
Professional end users	8	250

EXPOSURE DETAILS

Transport and storage
Transport, storage and warehouse workers are not expected to be exposed to the assessed chemical except in an unlikely event of accidental rupture of containers.

Reformulation
During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the assessed chemical at ≤ 1% concentration may occur during weighing, transfer, blending, quality control analysis, and cleaning and maintenance of equipment. The applicant states that exposure is expected to be minimised through the use of mechanical ventilation and enclosed systems, and through the use of personal protective equipment (PPE) such as protective clothing, goggles, impervious gloves and respiratory protection if required.

End-use
Exposure to the assessed 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 (e.g. hair dressers and workers in beauty salons), or the use of household products 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 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 assessed chemical.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the assessed 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 are also possible, particularly if products are applied by spray.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the assessed 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 irritation – *in vitro* EpiSkin™ reconstructed human epidermis test	non-corrosive
Skin irritation – *in vitro* SkinEthnic™ reconstructed human epidermis test	irritating
Eye irritation – *in vitro* EpiOcular™ test	non-irritating
Skin sensitisation – mouse local lymph node assay	evidence of sensitisation (EC3 = 18.9%)
Mutagenicity – bacterial reverse mutation	non mutagenic
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics
Given the low molecular weight of the assessed chemical (204 - 222 g/mol for the structural components identified), absorption across biological membranes may occur.

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

Irritation
In an *in vitro* study using the EpiSkin™ reconstructed human epidermis test model, the assessed chemical was found to be non-corrosive.

Based on the results of an *in vitro* study using SkinEthnic™ reconstructed human epidermis test model, the assessed chemical warrants classification as a Category 2 skin irritant under the GHS according to the test guideline.

In an *in vitro* eye irritation test using the EpiOcular™ test method, the assessed chemical was determined not to require classification for eye irritation under the GHS according to the test guideline.

Sensitisation
The assessed chemical was determined to be a weak skin sensitiser in a mouse local lymph node assay (LLNA) with stimulation indices of 1.16, 1.53, 2.01, 3.68 and 4.67 at 2.5%, 5%, 10%, 25% and 100%, respectively. The EC3 value (i.e. the estimated concentration of a test substance needed to produce a stimulation index of three) was calculated to be 18.9%.

Repeated Dose Toxicity
No repeated dose toxicity data were provided for the assessed chemical.

Mutagenicity/Genotoxicity
The assessed chemical was tested negative in two bacterial reverse mutation assays.

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

Hazard Classification	***Hazard Statement***
Skin Irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1B)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, the assessed chemical is a skin irritant and a weak skin sensitiser. Systemic effects following repeated exposure cannot be ruled out due to potential dermal absorption.

Reformulation
Workers may experience dermal, ocular and perhaps inhalation exposure to the assessed chemical at ≤ 1% concentration during reformulation. Skin irritation effects are not expected at the low introduction concentration. Given the assessed chemical is a weak skin sensitiser caution should be exercised when handling the assessed chemical during reformulation processes at 1% concentration.

Provided that control measures are in place to minimise worker exposure, including the use of enclosed, automated processes and PPE such as protective clothing, impervious gloves and respiratory protection (if inhalation exposure may occur), the risk to the health of workers during the handling of the assessed chemical is not considered to be unreasonable.

End-use
Cleaners and beauty care professionals will handle the assessed chemical at ≤ 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 assessed chemical at ≤ 0.1% concentration 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 assessed chemical through the use of cosmetic and household products containing the assessed chemical at ≤ 0.1% concentration.

Irritation and Sensitisation

The assessed chemical is a skin irritant and a weak skin sensitiser. However, irritation and sensitisation effects are not expected from the use of products containing the assessed chemical at low use concentrations (≤ 0.1%).

Repeated dose toxicity

The potential for systemic effects from repeated exposure to the assessed chemical is expected to be limited by the low concentrations (≤ 0.1%) of it in end use products.

Overall, based on the information available, the risk to the public associated with use of the assessed chemical at ≤ 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 assessed chemical will be imported into Australia as a component of fragrance oil formulations for local reformulation into finished cosmetic and household products. In general, the reformulation processes are expected to involve automated blending operations in an enclosed environment, followed by packing of the finished products into end-use containers. Release of the assessed chemical may be from spills during the transport, storage and product reformulation of the assessed chemical. Accidental spills and equipment washings are to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the assessed chemical will be rinsed into the sewer system as a result of its use in cosmetic and household products.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the assessed chemical in empty import and end-use containers are likely to either share the fate of the containers 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 majority of the assessed chemical is expected to enter the sewer system before potential release to surface waters on a nationwide basis. A ready biodegradation test determined that the assessed chemical is not readily biodegradable, but does significantly degrade (59% degradation after 28 days, and 78% by day 60). For details of the biodegradability study refer to Appendix C.

The assessed chemical is expected to be effectively removed at sewage treatment plants (STPs) due to its significant biodegradability. A proportion of the assessed 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. Minor amounts of the assessed chemical may also be disposed of to landfill as collected spills and empty container residues. The assessed chemical residues in landfill and soils are expected to have low mobility based on its estimated soil adsorption coefficient (log Koc = 3.1-4.3). Based on the log Pow (4.9-6.2), components of the assessed chemical have the potential to bioaccumulate; however, bioaccumulation is expected to be limited due to substantial degradation. In the aquatic and soil compartments, the assessed chemical is expected to 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 assessed 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 assessed chemical into sewer systems nationwide over 365 days per annum. The extent to which the assessed chemical is removed from the effluent in STP processes based on the properties of the assessed chemical has not been considered for this scenario, and therefore no removal of the assessed 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	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	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 assessed 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 0.56 µg/L may potentially result in a soil concentration of approximately 3.7 µg/kg. Since the assessed chemical is biodegradable (59% degradation in 28 d), no accumulation is expected.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the assessed chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity Study 1	EL50 = 0.998 mg/L WAF*	Very toxic to aquatic invertebrates
Daphnia Toxicity Study 2	EL50 = 0.835 mg/L WAF*	Very toxic to aquatic invertebrates
Algal Toxicity	ErL50 = 63.816 mg/L WAF*	Harmful to algae

*Water Accommodated Fraction

Based on the above ecotoxicological endpoints, the assessed chemical is expected to be very toxic to aquatic invertebrates and harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the assessed chemical is formally classified as "Acute Category 1; Very toxic to aquatic life". As the assessed chemical is significantly biodegradable, no classification for chronic toxicity was made.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using the most sensitive species for the assessed chemical. As two studies have been submitted for daphnia the geometric mean of the values has been used to represent the toxicity to daphnia (Daphnia, EL50 = 0.913 mg/L). An assessment factor of 500 was used given acute endpoints for two trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 for daphnia*	0.913	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	1.83	µg/L

* Geometric mean of two studies

7.3. Environmental Risk Assessment

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

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q – River	0.56	1.83	0.31
Q – Ocean	0.06	1.83	0.03

The risk quotient for a worst case discharge of treated effluent containing the assessed chemical to the aquatic environment indicates that the assessed chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. On the basis of the PEC/PNEC ratio, the assessed chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point < -20 °C

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	In a pre-test, the test substance was solid at -80 °C. The freezing point was therefore determined to be < -20 °C according to the guidelines.
Test Facility	LAUS GmbH (2017a)

Boiling Point Decomposes prior to boiling

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Determined using differential scanning calorimetry. The test substance decomposed without boiling at temperatures above 301.38 °C. The beginning of boiling under decomposition was determined as an exothermic event at 309.92 °C.
Test Facility	LAUS GmbH (2017b)

Density 976.3 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Determined using a pycnometer
Test Facility	LAUS GmbH (2017c)

Vapour Pressure 3.49 x 10^{-1} kPa at 20 °C
4.27 x 10^{-1} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure
Remarks	Determined by static method
Test Facility	LAUS GmbH (2017d)

Flash Point 145.5 °C at 101.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Determined using Pensky Martens apparatus
Test Facility	LAUS GmbH (2017e)

Autoignition Temperature 255 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Remarks	Determined by using the apparatus described in DIN 51794
Test Facility	LAUS GmbH (2018)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001)
Species/Strain	Rat/Sprague Dawley (SPF Caw)
Vehicle	None
Remarks – Method	No significant protocol deviation.

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	An increase in salivation was noted in one animal (Group 2) between 30 minutes to 3 hours post administration.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks – Results	All animals showed expected body weight gains during the observation period
CONCLUSION	The assessed chemical is of low acute toxicity via the oral route.
TEST FACILITY	PBD (2010)

B.2. Skin Irritation – *In Vitro* EpiSkin™ Reconstructed Human Epidermis Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 431 *In vitro* Skin Corrosion – Human Skin Model Test (2004) EpiSkin™ Reconstructed Human Epidermis Model
Vehicle	None
Remarks – Method	No significant protocol deviations. Positive and negative controls were run in parallel with the test substance: − Negative control (NC): distilled water − Positive control (PC): 8 N potassium hydroxide

RESULTS

Test Material	*Mean OD_{570} of Duplicate Tissues*		*Relative Mean Viability (%)*	
	3 min	*1 hr*	*3 min*	*1 hr*
Negative control	0.464	0.523	100	100
Test substance	0.460	0.555	99.0	106.2
Positive control	0.161	0.057	34.7	10.9

OD = optical density

Remarks – Results	In comparison to the negative control, the mean viability of the test substance treated tissues was 99% and 106.2% after an exposure period of 3 minutes and 1 hour, respectively. According to the study guideline, based on the mean tissue viability of ≥ 50% and ≥ 15% after 3 minutes and 1 hour exposure, respectively, the assessed chemical is non-corrosive. The positive and negative controls gave satisfactory results, confirming the validity of the test.

CONCLUSION	The assessed chemical was considered non-corrosive to the skin under the conditions of the test.
TEST FACILITY	PBD (2009a)

B.3. Skin Irritation – *In Vitro* SkinEthnic™ Reconstructed Human Epidermis Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method (2015) SkinEthnic™ Reconstructed Human Epidermis Model
Vehicle	None
Remarks – Method	No significant protocol deviations. The test chemical showed to be able to directly reduce MTT and therefore killed control tissues were tested in parallel with viable tissues. The results of the spectral analysis of the test substance showed the mean of the corrected OD to be less than 0.08 and therefore no colour correction controls were added to the study. Positive and negative controls were run in parallel with the test substance: Negative control (NC): Dulbecco's Phosphate buffered saline Positive control (PC): sodium dodecyl sulphate (5% in distilled water)

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	1113	100	± 0.7
Test substance	- 0.03*	- 2.7*	± 0.5
Positive control	0.014	1.3	± 0.1

*Mean corrected value for test substance; OD = optical density; SD = standard deviation;

Remarks – Results	As the mean tissue viability was ≤ 50%, the test substance was considered an irritant under the conditions of the test. The positive and negative controls gave satisfactory results, confirming the validity of the test.
CONCLUSION	Based on the mean tissue viability of ≤ 50%, the assessed chemical should be classified for skin irritation (Category 2) according to the GHS criteria.
TEST FACILITY	PBD (2017a)

B.4. Eye Irritation – *In Vitro* EpiOcular™ Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 492 Reconstructed Human Cornea-Like Epithelium (RhCE) Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage (2015) EpiOcular™ test system
Vehicle	None
Remarks – Method	No significant protocol deviations. The test chemical showed to be able to directly reduce MTT and therefore killed control tissues were tested in parallel with viable tissues. The results of the spectral analysis of the test substance showed the mean of the corrected OD to be less than 0.08 and therefore no colour correction controls were added to the study. Positive and negative controls were run in parallel with the test substance:

Negative control (NC): Distilled water
Positive control (PC): Methyl acetate

RESULTS

Test Material	*Mean OD_{570} of Duplicate Tissues*	*Relative Mean Viability (%)*
Negative Control	0.959	100
Test Substance	0.709*	73.93*
Positive Control	0.376	39.16

*Mean corrected value for test substance; OD = optical density

Remarks – Results: The relative mean viability for the test substance was 73.93%. As the relative mean tissue viability for the test substance was above 60%, it is considered a non-irritant according to the test guideline.

The positive and negative controls gave satisfactory results, confirming the validity of the test.

CONCLUSION: The assessed chemical is not considered an eye irritant requiring classification of it under the GHS criteria.

TEST FACILITY: PBD (2017b)

B.5. Skin Sensitisation – LLNA

TEST SUBSTANCE: Assessed chemical

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2002)
Species/Strain: Mouse/CBA/J
Vehicle: Acetone/olive oil (4:1 v/v)
Preliminary study: Yes
Positive control: Not conducted in parallel with the test substance, but had been conducted separately in the test laboratory using α-hexylcinnamaldehyde (95%).
Remarks – Method: No significant protocol deviation. A preliminary test was conducted using undiluted test substance to justify the concentrations for the main study. Based on these results, 100% was chosen as the high dose for the main study as it did not induce any systemic toxicity or excessive local irritation.

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
Experiment I			
Test Substance			
0 (vehicle control)	4 F	21.50	1.00
5%	4 F	32.98	1.53
10%	4 F	43.18	2.01
25%	4 F	79.08	3.68
100%	4 F	100.50	4.67
Experiment II			
Test substance			
0 (vehicle control)	4 F	19.94	1.00
2.5%	4 F	23.19	1.16

EC1.4 4.12%
EC3 18.9%

Remarks – Results	No mortalities and no signs of systemic toxicity were noted in the test or control animals during the study. Body weight gain of test and control animals between day 1 and 6 were comparable. Slight dryness to dryness was noted in all animals treated with 10%, 25% and 100% test substance on day 6. An increase in the mean ear thickness was observed in test animals at 25% (24.8% increase than day 1) and 100% (14.3% increase than day 1) concentrations on day 6. Treatment related increase in the mean ear weight was also noted in test animals at 25% (13% increase than day 1) and 100% (14.3% increase than day 1) concentrations on day 6. According to the study guideline, as the percent increase in ear thickness between day 1 and 6 was of ≥ 10% and ≤ 30%, the assessed chemical is a slight irritant.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the assessed chemical.
TEST FACILITY	PBD (2009b)

B.6. Genotoxicity – Bacteria

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1997) Plate incorporation procedure (Test 1) and pre incubation procedure (Test 2)
Species/Strain	*Salmonella typhimurium*: TA1535, TA98, TA100, TA102, TA97a
Metabolic Activation System	S9 mix from Aroclor 1254-induced rat liver
Concentration Range in Main Test	Test 1 With or without metabolic activation: 0.05, 0.15, 0.5, 1.5, 5 and 150 µg/plate Test 2 With or without metabolic activation: 5, 9, 19, 38, 75 and 150 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks – Method	No significant protocol deviation. Positive control: With metabolic activation: 2-aminoanthracene (TA1535, TA100, TA102, TA97a) and benzo-a-pyrene (TA 98) Without metabolic activation: sodium azide (TA1535, TA100) and 4-nitro-o-phenylene-diamine (TA97a, TA98, TA102).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 150	≥ 150	Negative
Test 2	-	> 150	≥ 150	Negative
Present				
Test 1	-	> 150	≥ 150	Negative
Test 2	-	> 150	≥ 150	Negative

Remarks – Results	No biologically relevant increases in revertant colony numbers of any of the tester strains were observed during the tests in either the presence or absence of metabolic activation. The positive controls induced a significant increase of revertant colonies during the study indicating the validity of the test system.

CONCLUSION	The assessed chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	LAUS GmbH (2014)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test (1997) Plate incorporation procedure (Test 1) and pre incubation procedure (Test 2)
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100; and *Escherichia coli*: WP2 uvrA
Metabolic Activation System	S9 mix from Aroclor 1254-induced rat liver
Concentration Range in Main Test	Test 1 With or without metabolic activation: 0.06, 0.19, 0.56, 1.67, 5 µL/plate Test 2 With or without metabolic activation: 0.06, 0.19, 0.56, 1.67, 5 µL/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks – Method	No significant protocol deviation. Positive control: With metabolic activation: 2-aminoanthracene (all strains) Without metabolic activation: sodium azide (TA1535, TA100), 2-nitrofluorene (TA98), 9-aminoacridine (TA1537) and 4-nitroquinoline-N-oxide (WP2 uvrA).

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5	> 5	Negative
Test 2	-	> 5	> 5	Negative
Present				
Test 1	-	> 5	> 5	Negative
Test 2	-	> 5	> 5	Negative

Remarks – Results	No biologically relevant increases in revertant colony numbers of any of the tester strains were observed during the tests in either the presence or absence of metabolic activation. The positive controls induced a significant increase of revertant colonies during the study indicating the validity of the test system.
CONCLUSION	The assessed chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Vivotecnia (2009)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated sludge
Exposure Period	60 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical oxygen demand (ThOD)
Remarks – Method	Conducted in compliance with GLP standards and principles. No major deviations from the test guidelines were reported. Sodium benzoate was used as a reference substance. A toxicity control was also conducted.

RESULTS

Test Substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
14	34	14	77
28	59	28	77
60	78	60	78

Remarks – Results	All validity criteria of the test guideline were satisfied. The percentage degradation of the reference compound (sodium benzoate) surpassed the threshold level of 60% after 14 days (77%). Therefore, the tests indicate the suitability of the inoculums. Oxygen uptake was 27.5 mg O_2/L in 28 days and did not exceed 60 mg/L. The pH was maintained between 7.4 – 7.9. The percentage biodegradation in the toxicity control at day 28 was 59%, hence it was concluded the test substance was not readily biodegradable. The test substance degraded to 60% and 78% after 30 and 60 days, respectively but did not reach the pass level at the end of the 10 days window.
CONCLUSION	The assessed chemical is not readily biodegradable.
TEST FACILITY	Ibacon (2017)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Aquatic Invertebrates Study 1

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Semi static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks – Method	The test was conducted according to good laboratory practice (GLP) principles. The definitive test was conducted based on a range-finding test with no major deviations from the test guidelines. Test solutions were prepared as water accommodated fractions (WAFs) by slow-stirring to avoid production of dispersion. The test water was renewed daily. Potassium dichromate was used as a reference substance.

RESULTS

Nominal Concentration (mg/L)*	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
0.32	20	0	0
0.57	20	0	5
1.01	20	13	13
1.80	20	17	17
3.21	20	20	20

*WAF prepared at the given loading rate

EL50 0.998 (95% CL of 0.840-1.187) mg/L at 48 hours

Remarks – Results All validity criteria were fulfilled. In the control, no daphnids became immobilised nor trapped at the surface of the water or showed signs of stress. Dissolved oxygen concentration at the end of the test was ≥ 60% of the air-saturation value in controls and test vessels. WAFs were stable within or ± 20% of the initial TOC. The 48 h EL50 including the 95% confidence interval were calculated using the computer program ToxRat® professional. The 48 h EC50 for *D. magna* exposed to potassium dichromate was within the range of expected responses.

CONCLUSION The test substance is acutely toxic to aquatic invertebrates.

TEST FACILITY LPL (2017a)

C.2.2. Acute Toxicity to Aquatic Invertebrates Study 2

Test Substance Assessed chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – Semi static
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring Total organic carbon (TOC) analysis
Remarks – Method The test was conducted according to good laboratory practice (GLP) principles. No major deviations from the test guidelines were reported. Test solutions were prepared as water accommodated fractions (WAFs) by slow-stirring to avoid production of dispersion. The test water was renewed daily. Potassium dichromate was used as a reference substance.

RESULTS

Nominal Concentration (mg/L)*	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
0.32	20	0	0
0.57	20	1	3
1.01	20	15	15
1.80	20	18	19
3.21	20	20	20

*WAF prepared at the given loading rate

EL50 0.835 (95% CL of 0.708 – 0.986) mg/L at 48 hours

Remarks – Results	All validity criteria were fulfilled. In the control, no daphnids became immobilised nor trapped at the surface of the water or showed signs of stress. Dissolved oxygen concentration at the end of the test was ≥ 60% of the air-saturation value in controls and test vessels. WAFs were stable within or ± 20% of the initial TOC values. The 48 h EL50 including the 95% confidence interval were calculated using the computer program ToxRat® professional. The 48 h EC50 for *D. magna* exposed to potassium dichromate was within the range of expected responses.
CONCLUSION	The test substance is acutely toxic to aquatic invertebrates.
TEST FACILITY	LPL (2017b)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 201 Freshwater Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata* (green algae)
Exposure Period	72 hours
Concentration Range	Nominal: 1.0 -100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks – Method	The definitive test was conducted based on a range-finding test with no major deviations from the test guidelines. Test solutions were prepared as water accommodated fractions (WAFs) by slow-stirring to avoid production of a dispersion. A reference test with potassium dichromate was run.

RESULTS

Biomass		*Growth*	
EbL50 (mg/L at 72 h)	*NOEbL (mg/L)*	*ErL50 (mg/L at 72 h)*	*NOErL (mg/L)*
4.19 95% CI: 2.46-6.87	0.585	63.82 95% CI: 41.67-118.64	1.592

Remarks – Results	All validity criteria for the study were satisfied. The cell density in the control increased 195-fold within 72 hours. The mean coefficient of variation for section-by-section specific growth rates in the control cultures was 31.3%. The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 1.4%. Due to the complex nature of the WAFs and the assessed chemical, the results are based on the test nominal loading rates. The 72 h ErL50 was determined to be 63.8 mg/L. The 48 h EC50 for algae exposed to potassium dichromate was within the range of expected responses.
CONCLUSION	The test substance is harmful to algae.
TEST FACILITY	LPL (2018)

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