File No: LTD/1771

January 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Orrisate

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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/1771	Firmenich Limited	Orrisate	Yes	≤ 1 tonne per annum	Fragrance ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard classification	*Hazard statement*
Flammable Liquids (Category 3)	H226 - Flammable liquid and vapour
Skin Irritation (Category 2)	H315 – Causes skin irritation

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R38: Irritating to skin

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

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 – Harmful to aquatic life

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

Based on the available information, when used at ≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners or ≤ 0.5% in other household products, the notified chemical is not considered to pose an unreasonable risk to public health.

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - H226 - Flammable liquid and vapour
  - H315 – Causes skin irritation

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

- Due to the flammable properties of the notified chemical, the notifier should consider their obligations under the Australian Dangerous Goods Code.

- The Delegate (and/or the Advisory Committee on Chemicals Scheduling) should consider the notified chemical for listing on the SUSMP.

(Material) Safety Data Sheet

- The (M)SDS provided by the notifier should be amended as follows:
  - The (M)SDS for the notified chemical should reflect the hazards associated with the notified chemical, as noted above.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed, automated processes, where possible
  - Ventilation system, including 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 inhalation

- 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, eye protection and coveralls

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

- A copy of the (M)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 for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Public Health

- The following measures should be taken formulators to minimise public exposure to the notified chemical:
  - The notified chemical should only be used at ≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners or ≤ 0.5% in other household products.

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.

Storage

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

Emergency procedures

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

Transport and Packaging

- The transport and packing of the notified chemical should be in accordance with State and Territory laws based on the requirements under the *Australian Code for the Transport of Dangerous goods by Road and Rail* (ADG Code) (NTC, 2014).

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 concentration of the notified chemical exceeds or is intended to exceed 0.5% in fine fragrances, 0.5% in other cosmetic products, 5% in air fresheners or 0.5% in other household products;
- additional information becomes available on the repeated dose toxicity potential of the notified chemical.

or

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

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Firmenich Limited (ABN: 86 002 964 794)
73 Kenneth Road
BAGOWLAH NSW 2093

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant, flammability, explosive properties and oxidising properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2014), Canada (2005), EU (2010), Korea (1997) and Philippines (2006).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Orrisate

MOLECULAR WEIGHT
< 200 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Measured
Boiling Point	173 °C at 97.4 kPa	Measured
Density	873 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.157 kPa at 25 °C	Measured
Water Solubility	0.12 g/L at 25 °C	Calculated (WSKOW v1.42; US EPA, 2011)
Hydrolysis as a Function of pH	Hydrolytically stable	Measured
Partition Coefficient (n-octanol/water)	log Pow = 3.37	Measured
Adsorption/Desorption	log K_{oc} = 2.0 (MCI method) log K_{oc} = 2.7 (Kow method)	Calculated by log Kow method (KOCWIN v2.00; US EPA, 2011)

Dissociation Constant	Not determined	Contains no dissociable functionalities.
Flash Point	57 °C at 101.3 kPa	Measured
Autoignition Temperature	> 220 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Flammable Liquids (Category 3)	H226 - Flammable liquid and vapour

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia either in neat form or as a component of fragrance formulation for reformulation.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Firmenich (outside Australia)
Recipient: Firmenich Limited

TRANSPORTATION AND PACKAGING
The notified chemical will be imported either in neat form, as a component of fragrance formulation for reformulation, or as a component of formulated end-use products. The notified chemical or products containing the notified chemical will be transported from the port of entry to the notifier's warehouse facilities by road and will be delivered typically by road to clients' facilities.

USE
The notified chemical will be used as a fragrance ingredient in cosmetics (≤ 0.5% in fine fragrances and ≤ 0.5% in other cosmetic products) and household products (≤ 5% in air fresheners and ≤ 0.5% in other household products).

OPERATION DESCRIPTION
The processes for incorporating the imported notified chemical in neat form or as a component of fragrance preparations into end-use products will likely vary depending on the nature of the cosmetic and household products being formulated, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and occur in enclosed environments, followed by automated filling of the reformulated products into containers of various sizes.

The finished products containing the notified chemical at ≤ 5% concentration may be used by consumers and professionals such as workers in beauty salons 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 workers	unknown	unknown
Mixing	4	2
Drum Handling	4	2
Drum Cleaning	4	2
Maintenance	4	2
Quality Control	0.5	1
Packaging	4	2

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified chemical in neat form, as a component of the imported fragrance preparations or end-use products (≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners and ≤ 0.5% in other household products), only in the event of accidental rupture of containers.

During reformulation of the notified chemical into the final consumer products, dermal, ocular and inhalation exposure of workers (at ≤ 100% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of local and general ventilation and/or enclosed systems and through the notifier stated use of personal protective equipment (PPE) such as gloves, respirator, eye protection and uniform.

Exposure to the notified chemical in end-use products (≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners or ≤ 0.5% in other household products) may occur in professions where the services provided involve the application of cosmetic products to clients (e.g. workers in beauty salons) or in the cleaning industry. Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical (≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners or ≤ 0.5% in other household products) through the use of the household products and the rinse-off and leave-on cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

A combined internal dose of 1.4573 mg/kg bw/day was estimated using data on typical use patterns of cosmetic and household cleaning product categories in which the notified chemical may be used (SCCS, 2010; Cadby *et al.*, 2002; SDA, 2005; specific use details of the notified chemical are considered as exempt information). This estimation assumed a worst case scenario and is for a person who is a simultaneous user of a selection of cosmetic and household products that may contain the notified chemical.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*

Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; harmful*
Rat, acute dermal toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic

* Based on deaths of four of 10 animals at the dose level of 2000 mg/kg bw and little apparent toxicity at the dose level of 500 mg/kg bw.

Toxicokinetics.
Based on the water solubility (0.144 g/L at 25 ºC), partition coefficient (log P_{ow} = 3.37) and the low molecular weight (< 200 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption could occur. The notified chemical may also be absorbed across the respiratory tract.

Acute toxicity.
There were two acute oral studies conducted in rats provided by the notifier, with the notified chemical found to be of low toxicity in one study and harmful in the other. In one study (TLL, 1989) at a dose level of 2000 mg/kg bw, 3 female animals and 1 male animal either died or were euthanized prior to the study concluding due to adverse effects, at the dose level of 500 mg/kg bw there were no deaths. In a second study (PSL, 2003a) there were no deaths at 2000 mg/kg bw. The only significant difference between the two studies was that corn oil was used as the vehicle in the older study, whereas the notified chemical was administered undiluted in the latter study. While deaths occurred at the dose level of 2000 mg/kg bw in the first study (TLL, 1989), no abnormalities were noted at necropsy and hence the cause of death is unknown. Since the second study (PSL, 2003) fulfilled all the test criteria in accordance with OECD test guidelines 425 and is a significantly more recent study, the notified chemical is considered to be of low toxicity.

In a study conducted in rats he notified chemical was found to be of low toxicity (LD50 > 5000 mg/kg bw) via the dermal route.

Irritation and sensitisation.
Based on studies conducted in rabbits the notified chemical was irritating to the skin and slightly irritating to eyes.

The notified chemical at concentrations up to 100% (intradermal induction concentration of 5%, topical induction concentration of 100% and topical challenge concentration of 50%) showed no evidence of skin sensitisation in guinea pigs.

Repeated dose toxicity.
There are no repeat dose toxicity data available for the notified chemical.

The predicted primary metabolite (identity in Exempt Information) of the notified chemical has a NOAEL in rats of 250 mg/kg bw/day. In the absence of adequate data on the chronic toxicity of the notified chemical, data on this predicted metabolite will be used to conduct the quantitative risk assessment.

Mutagenicity/Genotoxicity.
The notified chemical was negative in a bacterial reverse mutation assay.

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

Hazard classification	***Hazard statement***
Skin Irritation (Category 2)	H315 – Causes skin irritation

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R38: Irritating to skin

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Beauticians, cleaners and sales workers may be exposed to the notified chemical at various concentrations when applying products containing it to clients. The risk for beauty care professionals who regularly use products containing the notified chemical is expected to be similar to that experienced by members of the public who use such products on a regular basis. For details of the public health risk assessment, see Section 6.3.2.

Workers involved in the reformulation of the imported products into cosmetic products may be exposed to the notified chemical at concentrations up to 100%. Exposure is expected to be limited during product reformulation by the engineering controls and the use of PPE as stated by the notifier.

Under the proposed occupational settings the notified chemical is not considered to pose an unreasonable risk to workers.

6.3.2. Public Health

The general public will be repeatedly exposed to the notified chemical during the use of both rinse-off and leave-on cosmetics and household products containing the notified chemical at various concentrations.

Local effects

The notified chemical is irritating to the skin and slightly irritating to eyes. However at the low proposed end use concentrations skin and eye irritation effects are not expected.

Systemic effects

The potential systemic exposure to the public from the use of the notified chemical in cosmetic and household products was estimated to be 1.4573 mg/kg bw/day. Using a NOAEL of 250 mg/kg bw/day, which was derived from toxicity studies on the predicted primary metabolite of the notified chemical, the margin of exposure (MOE) was estimated to be 172. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences, therefore, the MOE is considered to be acceptable.

The repeated dose toxicity effects of the notified chemical have not been determined. It is acknowledged that there is uncertainty in the estimated MOE, due to the use of the NOAEL for the predicted primary metabolite. However, exposure will be limited by the low concentration of the notified chemical in end-use products for which the primary route of exposure is dermal.

Therefore, based on the information available, the risk to the public associated with the use of the notified chemical at ≤ 0.5% in fine fragrances, ≤ 0.5% in other cosmetic products, ≤ 5% in air fresheners or ≤ 0.5% in other 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 not be manufactured in Australia; therefore there is no release of the notified chemical to the environment from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified chemical is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

During reformulation processes, limited release of the notified chemical is expected from cleaning of equipment as washings will be reused. A total of up to 0.2% of the import volume is estimated to be generated as waste from residues in empty containers and spills during reformulation. Empty containers containing the notified chemical will either be recycled or disposed of through an approved waste management facility.

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 domestic products, which are washed off the hair and skin of consumers as well as from cleaning activities and disposed of to the sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that some of the product containing the notified chemical will remain in end-use containers. The containers are expected be disposed of through domestic garbage disposal and will enter landfill, or be subjected to recycling processes.

7.1.2. Environmental Fate

Following its use in Australia, the majority of the notified chemical is expected to enter the sewer system before potential release to surface waters on a nationwide basis. The notified chemical is hydrolytically stable based on the study provided. There are two biodegradation studies provided by the notifier. One study indicated that the notified chemical is not considered to be rapidly degradable in the environment. However, the other study indicated that the notified chemical is considered to be rapidly degradable in the environment. Since the study which showed the ready biodegradability of the notified chemical fulfilled all the test criteria and validity, the notified chemical is considered readily biodegradable and hence, it is expected to be significantly degraded during the wastewater treatment process. Based on its low adsorption coefficient value (log K_{oc} = 2.0 – 2.7), only limited partitioning to sludge is expected. The notified chemical has low potential to bioaccumulate based on its low partition coefficient (log Pow = 3.37). In surface waters, the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon.

The notified chemical is expected to have high volatility from water (log H = 97 Pa/m^3/mol) and may likely to volatilise to air during use or sewage treatment based on calculations for a representative component of the notified chemical. In the event of release to the atmosphere, the notified chemical is not expected to persist in the air compartment based on calculations (AOPWIN v1.92; US EPA, 2011) for a representative component of the notified chemical.

A proportion of notified chemical may be applied to land when effluent is used for irrigation, or disposed of to landfill as waste. Notified chemical residues in landfill and soils are expected to have moderate mobility based on its low soil adsorption coefficient. In the aquatic and soil compartments, the notified chemical is expected to slowly degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in cosmetics and household cleansing products, it is assumed that 100% of the total import volume of the notified chemical is released to the sewer. The release is assumed to be nationwide over 365 days per year. It is conservatively assumed that 0% of the notified chemical will be removed during sewage treatment processes.

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)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	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 0.61 µg/L may potentially result in a soil concentration of approximately 4.0 µg/kg from each

year of irrigation. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

Ecotoxicological data were submitted for the notified chemical. Details of the studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish (96 h)	LC50 = 20.7 mg/L	Harmful to fish
Daphnia Toxicity (48 h)	EC50 = 23.8 mg/L	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	E_rC50 > 14.8 mg/L	Harmful to algae

The notified chemical is considered to be harmful to fish, aquatic invertebrates and algae. On the basis of the acute toxicity data, the notified chemical is harmful to aquatic organisms. Therefore, Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified chemical is formally classified as Acute Category 3; Harmful to aquatic life. Based on its acute toxicity, ready biodegradability and log Kow < 4, the notified chemical has not been formally classified under GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the most sensitive species (algae, E_rC50) for the notified chemical. Acute ecotoxicity endpoints for aquatic species from three trophic levels are available. Therefore, an assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	> 14.80	mg/L
Assessment Factor	100	
PNEC:	> 148.00	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.61	> 148	< 0.004
Q - Ocean:	0.06	> 148	< 0.000

The risk quotient for discharge containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations based on its reported use pattern and annual importation quantity. The notified chemical has low potential for bioaccumulation. Therefore, on the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern in cosmetic and domestic products, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks Determined by temperature sensor
Test Facility Firmenich (2003)

Boiling Point 173 ± 0.5 °C at 97.4 kPa

Method OECD TG 103 Boiling Point.
Remarks Determined by temperature sensor
Test Facility Firmenich (2003)

Density 873 kg/m^3 at 20 ± 0.5 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Determined by changes of resonance frequency of oscillator
Test Facility Firmenich (2003)

Vapour Pressure 0.157 kPa at 25 °C

Method OECD TG 104 Vapour Pressure.
Remarks Determined using vapour pressure balance
Test Facility Firmenich (1998)

Hydrolysis as a Function of pH Hydrolytically stable

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ < days>*
2	25	Not reported
5	25	Not reported
7	25	Not reported
8.5	25	Not reported
12	25	Not reported

Remarks The decrease in concentration of the test substance after 5 days was less than 10% at pH 2 to 8.5 at 40 °C. The test substance is considered hydrolytically stable under the environmental pH range of 4 to 9 according to OECD TG 111.
Test Facility Firmenich (2014)

Partition Coefficient (n-octanol/water) log Pow = 3.37

Method OECD TG 117: Partition Coefficient (n-octanol/water), HPLC Method.
Remarks HPLC Method
Test Facility Firmenich (2007)

Flash Point 57 ± 2 °C at 101.3 kPa

Method EC Directive92/69/EEC A.9 Flash Point.
Remarks Open cup
Test Facility Firmenich (2003)

Autoignition Temperature > 220 °C

Method In-house.
Remarks Determined by automatic AIT instrument
Test Facility Firmenich (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 425 Acute Oral Toxicity – Up-and-Down Procedure – Limit Test.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: None
- Remarks - Method: No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5F	2000	0/5

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: Hypoactivity, piloerection and reduced fecal volume were noted in two animals on day 0-1.
- Effects in Organs: No abnormalities were noted at necropsy.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: PSL (2003a)

B.2. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Corn oil
- Remarks - Method: The first limit test was conducted at 2000 mg/kg bw and the second limit test was conducted at 500 mg/kg bw due to mortality at the dose level of 2000 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	4/10
2	5per sex	500	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: At the dose level of 2000 mg/kg bw, 2 female animals were humanely killed 7 hours after dosing as death was considered to be inevitable. One male animal was found dead on Day 2 and one female animal on Day 4. Hypoactivity and hunched posture were noted in one female animal. At the dose level of 500 mg/kg bw, excessive salivation was noted in 2 male animals from 30 minutes until 4 hours after dosing. Piloerection, hypoactivity and hunched posture were noted in all male animals on the day of dosing. All animals recovered by Day 2.
- Effects in Organs: No abnormalities were noted at necropsy at either dose level.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: TLL (1989)

B.3. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	ECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity - Local	Only dermal irritation (erythema and edema) were noted at the dose site of all animals between Day 1 and Day 3.
Signs of Toxicity - Systemic	No signs of adverse pharmacologic effects or abnormal behaviour were noted.
Effects in Organs	No gross abnormalities were noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	PSL (2004)

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand albino
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive
Remarks - Method	Intact skin sites on each animal were tested with 0.5 mL of the test substance using a 4 hour exposure period. Observations were recorded at 1, 24, 48 and 72 hours and at 7, 10 and 14 days after patch removal.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	4	3.3	3.3	4	> 14 days	3
Oedema	1.7	1.7	1.7	3	> 14 days	3

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Within 24 hours of patch removal, severe erythema and very slight edema were noted at all treated sites. Desquamation was noted for 2 animals between Day 10 and Day 14. Although the overall severity of irritation decreased gradually by the end of the study, irritation persisted for all animals through Day 14.
CONCLUSION	The notified chemical is irritating to the skin.
TEST FACILITY	PSL (2003b)

B.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand albino
Number of Animals 3
Observation Period 72 hours
Remarks - Method 0.1 mL of test substance was instilled into the right eyes of the test animals.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.7	0.7	0.3	2	< 72 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results No corneal effects or iritis were noted.
Slight conjunctiva redness was noted in all animals from 1 hour until a maximum of the 48 hour observation.
Conjunctival chemosis or ocular discharge was not noted.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY PSL (2003c)

B.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation - Magnusson and Kligman.
Species/Strain Guinea pig/Hartley albino
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 50% (w/w) in mineral oil
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 5
INDUCTION PHASE Induction Concentration:
intradermal: 5% (w/w) in mineral oil
topical: 100%
Signs of Irritation Faint to moderate erythema (1-2) was noted at all test sites 1 hour after removal of the topical induction patch.
CHALLENGE PHASE Topical: 50% (w/w) in mineral oil
Remarks - Method No significant protocol deviations

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	50%	5	4
Control Group	50%	2	2

Remarks - Results One treated animal died during the study, necropsy findings included

stomach distension, discoloration of the intestines and heart and anal discharge. Very faint erythema (0.5) was noted at 5 of 9 test sites 24 hours following the challenge patch removal and similar irritation persisted at 4 sites through 48 hours. The result was comparable to that in the control group where very faint erythema (0.5) was noted at 2 of 5 sites at 24 hours following the challenge patch removal and similar irritation persisted at the 2 sites through 48 hours. Eight of 10 historical positive control animals exhibited faint to severe erythema (1-3) 24 hours following the challenge patch removal and similar indications persisted at 7 sites through 48 hours while 3 of 5 control group animals exhibited very faint erythema (0.5) 24 hours following the challenge patch removal and free of irritation by 48 hours.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY PSL (2003d)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System S9 mix

Concentration Range in Main Test a) With metabolic activation: 0, 75, 200, 600, 1800, 5000 µg/plate
b) Without metabolic activation: 0, 75, 200, 600, 1800, 5000 µg/plate

Vehicle Ethanol

Remarks - Method Two preliminary toxicity tests (0-5000 µg/plate) were performed to determine the toxicity of the test substance.
In the mutation study, aliquots of 0.05 mL of either test substance, negative control solution or positive control solution were used at 5 concentrations up to 5000 µg/plate. The negative control was ethanol and positive controls were 2-nitrofluorene, sodium azide, 9-aminoacridine and methyl methanesulfonate in the absence of S9 mix and 2-aminoanthracene in the presence of S9 mix.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2	> 5000		> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2	> 5000		> 5000	Negative

Remarks - Results

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BioReliance (2003)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
- Inoculum: Activated Sludge
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: Oxygen electrode to measure the dissolved oxygen
- Remarks - Method: The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	12.0	7	67.9
14	25.2	14	70.7
28	24.7	28	78.5

Remarks – Results: All validity criteria for the test were satisfied. The reference compound, sodium benzoate, achieved > 67% degradation by Day 7, and therefore the test is considered valid for this criterion. It was not indicated in the study that a toxicity control was included. The degree of degradation of the notified chemical after the cultivation period was 24.7%. Therefore, the test substance is classified as not readily biodegradable according to the OECD (301 D) guideline.

CONCLUSION: The notified chemical is not readily biodegradable.

TEST FACILITY: ABC (2004a)

C.1.2. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
- Inoculum: Activated Sludge
- Exposure Period: 28 days
- Auxiliary Solvent: None
- Analytical Monitoring: Oxygen electrode to measure the dissolved oxygen
- Remarks - Method: The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	58.0	7	70.0
14	62.0	14	76.0
28	84.0	28	Not reported

Remarks – Results: All validity criteria for the test were satisfied. The reference compound, sodium acetate, achieved 70% degradation by Day 7, and therefore the test

	is considered valid for this criterion. It was not indicated in the study that a toxicity control was included. The test substance passed the criterion for ready biodegradability of > 60% degradation (CO_2) reached within the 10 day window. The degree of degradation of the notified chemical after the cultivation period was 84%. Therefore, the test substance can be classified as readily biodegradable according to the OECD (301 D) guideline.
CONCLUSION	The notified chemical is readily biodegradable.
TEST FACILITY	AkzoNobel (2004)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203: Fish, Acute Toxicity Test – Static Test
Species	Rainbow Trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	144 mg $CaCO_3$/L
Analytical Monitoring	GC Analysis
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. All test treatments, with the exceptions of the two highest treatments, appeared clear and colourless. Surface films were observed at the two highest test treatments.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Cumulative mortality (%)*			
Nominal	*Mean measured*		*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	20	0	0	0	0
3.3	2.68	20	0	0	0	0
6.5	5.03	20	0	0	0	0
13	10.2	20	0	0	0	0
25	16.0	20	10	10	10	10
50	29.7	20	100	10	100	100

LC50	20.7 (19.2 – 22.2) mg/L at 96 hours
NOEC	10.2 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The actual concentrations of the treatment were measured at the beginning and end of the test. The 96-hour LC50 was calculated based on the mean measured concentrations of 0 and 96 hours, by trimmed Spearman-Karber method.
CONCLUSION	The notified chemical is harmful to fish.
TEST FACILITY	ABC (2004b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not reported

Water Hardness	250 mg $CaCo_3$/L
Analytical Monitoring	GC Analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. All test treatments appeared clear and colourless.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Cumulative % Immobilised*	
Nominal	*Mean measured*		*24 h*	*48 h*
Control	Control	20	0	0
3.3	2.06	20	0	0
6.5	4.11	20	0	0
13	7.37	20	0	0
25	18.7	20	0	0
50	30.3	20	55	100

LC50	23.8 (18.7 – 30.3) mg/L at 48 hours
NOEC (or LOEC)	18.7 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The treatments concentrations were measured at the beginning and end of the test. The 48-hour EC50 was calculated based on the mean measured concentrations of 0 and 48 hours, by trimmed Spearman-Karber method.

CONCLUSION The notified chemical is harmful to aquatic invertebrates.

TEST FACILITY ABC (2004c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Concentration Range	Nominal: 1.7, 3.3, 6.5, 13, 25, and 50 mg/L Time-weighted average measured: 0.561, 1.07, 1.92, 3.53, 6.02 and 14.8 mg/L
Auxiliary Solvent	Not reported
Water Hardness	24 mg $CaCo_3$/L
Analytical Monitoring	GC Analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yC50 (mg/L)	*NOE_yC (mg/L)*	*E_rC50 (mg/L)*	*NOE_rC (mg/L)*
> 14.8	14.8	> 14.8	14.8

Remarks - Results	All validity criteria for the test were satisfied. The treatments concentrations were measured at the beginning and every 24 hours until the end of the test. The end points were determined based on the time-weighted average measured concentrations. The test was conducted for 96 hours; however the 72-hour test endpoints are presented as standard. The endpoints were calculated using SAS statistical software.

CONCLUSION	The notified chemical is harmful to algae.
TEST FACILITY	ABC (2004d)

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