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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

HIVERNAL

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Firmenich Limited (ABN 86 002 964 794)
73 Kenneth Road,
Balgowlah 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, Spectral data, Method of detection and determination, Degree of purity, Identity and weight percent of non-hazardous impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for: Vapour pressure, Hydrolysis as a function of pH, Adsorption/desorption, Flammability and Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVCR/92 – permit

NOTIFICATION IN OTHER COUNTRIES
Switzerland, USA, Canada, EU, Philippines, Japan, South Korea and China.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
HIVERNAL (notified chemical)

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 80 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

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	-34.5°C	Measured
Boiling Point	301°C at 101.06 kPa	Measured
Density	1000 kg/m^3 at 20°C	Measured
Vapour Pressure	0.247x10^{-3} kPa at 25°C [8.73 × 10^{-5} kPa at 25°C]	Estimated [Estimated using MPBPVP (v1.43) (US EPA, 2009)]
Water Solubility	98 x10^{-3} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain any readily hydrolysable functionality and is therefore expected to be hydrolytically stable
Partition Coefficient (n-octanol/water)	log K_{OW} = 3.48 to 3.56 at 23°C	Measured
Adsorption/Desorption	log K_{OC} = 2.62 to 2.71	Estimated by KOCWIN (v2.00) (US EPA, 2009)
Dissociation Constant	Not determined	The notified chemical does not contain dissociable functionality
Particle Size	Not determined	Test not conducted as the notified chemical is a liquid.
Flash Point	>150°C at 101.3 kPa	Measured
Flammability	Not determined	No structural alert for both pyrophoricity and flammability with water, based on the chemical structure of the notified chemical.
Autoignition Temperature	360 ± 5°C	Measured
Explosive Properties	Not determined	Not expected to be explosive, based on the chemical structure of the notified chemical.

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

Reactivity
Stable under normal conditions of use.
Avoid temperature near or above the flash point. Avoid contact with oxidizing agent.

Dangerous Goods classification
Based on the limited submitted physical-chemical data in the above table, the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is not manufactured in Australia. It will be imported as a minor component of fragrance preparations at maximum of 0.1% concentration in tightly closed lacquered drums.

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
The fragrance preparations containing the notified chemical will be imported by Firmenich Ltd and will be distributed locally to other customers.

TRANSPORTATION AND PACKAGING
The fragrance preparations containing the notified chemical as a minor component (maximum of 0.1%) will be imported in tightly closed lacquered drums, typically of 180 kg size, but also in 5, 10, 25, 50 or 100 kg packages. The fragrance preparations will be transported by road from the wharf or airport of entry to the Firmenich Ltd warehouse for storage and then distributed to customers/manufacturers for incorporation/blending/formulation into a wide variety of cosmetics, toiletries and household products.

USE
The notified chemical will be used as a fragrance ingredient in a variety of cosmetic and domestic products. In final finished products, the concentration of the notified chemical will be at a maximum of 0.1% in fine perfumes and a maximum of 0.0025% in other cosmetic and domestic products.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia and will be imported in liquid compounded fragrances at a maximum of 0.1%. The fragrance preparations containing the notified chemical will be reformulated in Australia and will be used in cosmetics, household cleaning and detergent products.

The reformulation process mainly involves a blending operation which will be highly automated and will occur in a fully enclosed environment, followed by automatic filling in containers of various sizes. The final consumer products containing the notified chemical up to 0.1% will be distributed to retail outlets, displayed and sold to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	4	Unknown	unknown
Mixer	5	4	2
Drum handling	5	4	2
Drum cleaning	8	4	2
Maintenance	5	4	2
Quality control	1	0.5	1
Packaging	10	4	2
Salon workers	100	1	300

EXPOSURE DETAILS
The major occupational exposure to the notified chemical will be at the reformulation plants where the imported containers of fragrance mixtures containing the notified chemical (at a maximum of 0.1%) are opened and used. Workers may be exposed to fragrances containing the notified chemical during handling of the drums, weighing and charging them to the blending vessel, mixing in open vessels and also during cleaning operations, production line, and sampling or analysis tasks. Exposure via all three routes (dermal, ocular and inhalation) is anticipated to be minimal and not on regular basis. The number and category of workers will depend on the nature of the customers business.

Reformulation is usually done in fully automated systems, however some facilities may not be fully automated. Hazardous components of the products are mixed together and the size of the batches usually necessitate the use of closed lines, local exhaust ventilation where vapours or aerosols are produced, and automated packing

lines.

All workers handling perfume preparations containing the notified chemical and involved in open mixing operations will wear suitable gloves, eye or face protection and protective clothing. If open vessels are used for mixing, adequate ventilation is provided to remove aerosols that may arise during the process. It is very unlikely that the product containing the notified chemical at 0.1% will be added to the mixing vessel manually.

Workers in hair and beauty salons will experience extensive dermal exposure during application of products containing the notified chemical at only up to 0.0025% or less by hand. Such professionals may use some personal protective equipment to minimise repeated exposure, and good hygiene practices are expected to be in place. Exposure of such workers is expected to be of a similar or higher level than that experienced by consumers using products containing the notified chemical.

Overall, the exposure of workers to the notified chemical is expected to be low.

6.1.2. Public exposure

During importation, transport, storage and reformulation of fragrance compositions containing the notified chemical at up to 0.1% concentration, exposure of the general public will be limited, except in the event of an accidental spill.

Consumer products containing the notified chemical (fine fragrance, cosmetics and homecare products) will be sold in the public domain, consequently there is potential for widespread public exposure to very low concentration of the notified chemical. Exposure will be mainly via dermal route.

Overall, exposure to the notified chemical is considered minimal, given the very low concentration of notified chemical in the final consumer products.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 200 <LD50< 2000 mg/kg bw; harmful
Rabbit, skin irritation	slightly irritating with reversible effect
Rabbit, eye irritation	slightly irritating with reversible effect
Guinea pig, skin sensitisation – adjuvant test.	evidence of sensitisation
Guinea pig, skin sensitisation – Buehler test.	Not a skin sensitiser
Mutagenicity – bacterial reverse mutation	non mutagenic
Human Repeated Insult Patch Test (HRIPT)	non sensitising at 1% in DEP
Human Repeated Insult Patch Test (HRIPT)	non sensitising at 5% in DEP

Toxicokinetics, metabolism and distribution.

Given the notified chemical has a low molecular weight, a relatively low water solubility (98 $x10^{-3}$ g/L measured), an adsorption/desorption (log K_{OC} = 2.62 to 2.71 estimated) and a partition coefficient (log P_{ow} of 3.48 to 3.56 measured), dermal absorption is expected to be low.

Acute toxicity.

The notified chemical is harmful *via* the oral route (LD50 200 <LD50< 2000 mg/kg bw).

No acute dermal or inhalation toxicity study was conducted using the notified chemical. Inhalation toxicity is expected to be low as the notified chemical expected to have a low vapour pressure ($0.247x10^{-3}$ kPa estimated).

Irritation and Sensitisation.

The notified chemical was slightly irritating to skin and eyes with reversible effect when tested undiluted on rabbits. It was a skin sensitiser in Guinea pig “Magnusson & Kligman Maximisation” skin sensitisation adjuvant test.

The notified chemical showed no evidence of sensitisation in Guinea pig, in the Buehler test and also in Human

Repeated Insult Patch Tests at 1% in Diethyl Phthalate and at 5% in Diethyl Phthalate tests.

However, considering that the notified chemical showed skin sensitisation in "Magnusson & Kligman Maximisation" skin sensitisation adjuvant test, the notified chemical is considered a skin sensitiser.

Mutagenicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study.

Health hazard classification
Based on the data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

Xn; R22: Harmful if swallowed
Xi; R43: May cause sensitisation by skin contact

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary risk associated with the use of the notified chemical in cosmetics is its potential to cause skin sensitization. However, as the notified chemical will be imported at the maximum concentration of 0.1%, the risk of skin sensitization is not expected.

Furthermore, the use of highly automated and fully enclosed blending processes, automatic filling and personal protective equipment (PPE) worn by workers, will further reduce the occupational risk.

Overall, the risk posed to occupational health and safety of workers is not expected to be unacceptable.

6.3.2. Public health
Members of the public will experience widespread and frequent exposure to the notified chemical up to 1% concentration through daily use of cosmetic and domestic products. At this low concentration, no risks are expected. No information is available on repeat dose toxicity of the notified chemical to assess its repeat dose effects. However, based on the low concentration used in products, repeat dose risks are not expected.

Overall, based on the available data, the notified chemical is not expected to pose unacceptable risk to public health when used at up to 0.1% concentration in cosmetic and domestic products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of fragrance preparations for local reformulation into a variety of consumer products (cosmetics, household products, fine fragrance). Losses during the blending processes at various sites throughout Australia are expected to be limited to traces of spills, formulation equipment cleaning and residues in empty packaging. Less than 0.1 % of the total annual import volume of notified chemical is expected to remain as residues in import containers. The empty containers will eventually be recycled or disposed of to landfill. At the end of the reformulation run the formulating equipment and packing equipment is washed and it is anticipated that the washings will be included in the next batch.

Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Most of the notified chemical will be incorporated as a fragrance additive into a variety of consumer products for dispersed use throughout Australia. Whilst there will be some releases of this moderately volatile fragrance chemical to the atmosphere, the majority of the imported quantity of notified chemical is expected to be released to the sewer in domestic situations.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired wastes and residue of the notified chemical in empty containers (<0.1%) are likely either to share the fate of the container and be disposed of to landfill, or to be washed to the sewer when containers are rinsed before recycling.

7.1.2 Environmental fate

The notified chemical is a moderately volatile compound and some of the imported quantity of this chemical will partition to air, which is a functional requirement for fragment products. The half-life of the notified chemical in air was calculated to be ≤ 3.19 h, based on reactions with hydroxyl radicals over a 12 hour day, and reaction with ozone is not expected (AOPWIN, v1.92; EPISuite, US EPA 2009). The notified chemical is therefore not expected to persist in the air compartment.

The major proportion of the imported quantity of notified chemical will enter the sewer system as a result of the use of this chemical as an odorant in domestic consumer products such as cosmetics and household products. The notified chemical is not readily biodegradable although it is predicted to be removed from waste water treatment plants by up to 21% through adsorption to sludge (SimpleTreat; European Commission, 2003). In the case of release to surface waters, the notified chemical is expected to disperse and slowly degrade. It is not likely to bioaccumulate, based on its low molecular weight and low bioconcentration factor (log BCF ≤ 2.02) predicted by a regression-based method based on the maximum measured partition coefficient, log K_{OW} = 3.56 (BCFBAF v3.00; US EPA, 2009).

A small proportion of notified chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation. Notified chemical residues in landfill, soil and sludge are likely to be relatively mobile, and are expected to degrade biotically or abiotically to form water and oxides of carbon.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The following Predicted Environmental Concentrations (PEC) have been calculated assuming that all of the imported quantity of notified chemical is released to sewer and up to 21% is removed from waste water by sewage treatment plant (STP) processes before discharge to surface waters on a nationwide basis.

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)	21.161	million
Removal within STP	21%	**Mitigation**
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.51	µg/L
PEC - Ocean:	0.05	µg/L

Based on the Simple Treat (EC, 2003) modelling prediction of 21% partitioning to sludge, partitioning to biosolids in STPs Australia-wide may result in an maximum biosolids concentration of 1.359 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 9 µg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 45 µg/kg and 90 µg/kg, respectively.

Notified chemical that is not removed from waste water during STP processes may be released to the environment in STP effluent. 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 0.511 µg/L may potentially result in a soil concentration of approximately 3.409 µg/kg. 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 17.05 µg/kg and 34.09 µg/kg, respectively.

7.2. Environmental effects assessment

The acute toxicity for the notified chemical was estimated using the aldehydes (mono) structure-activity relationship (SAR) from the ECOSAR suite of models. The modelled estimates (ECOSAR (v1.00), aldehydes (mono) SAR, user entered log K_{OW} = 3.56; US EPA, 2009) for the acute and chronic endpoints of the notified chemical are tabulated below.

The inhibition of activated sludge respiration when in the presence of notified chemical was studied and the results are tabulated below. For details of this study, see Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish	96 h LC50 = 1.92 mg/L	Toxic to fish
Daphnia	48 h EC50 = 1.47 mg/L	Toxic to aquatic invertebrates
Algae	96 h EC50 = 3.75 mg/L	Toxic to algae
Chronic Toxicity		
Fish	32 d ChV‡ = 0.140 mg/L	Toxic to fish with long lasting effects
Daphnia	ChV‡ = 0.279 mg/L	Toxic to aquatic invertebrates with long lasting effects
Algae	96 h ChV‡ = 1.599 mg/L	Not harmful to algae

Inhibition of Bacterial Respiration	3 h IC50 > 100 mg/L	Not inhibitory to microbe respiration

‡ ChV (Chronic Value) = $(LOEC \times NOEC)^{½}$

Under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS), the notified chemical is considered to be toxic to fish, daphnia and algae. Based on its acute toxicity to aquatic biota, the notified chemical is formally classified under the GHS as 'Acute Category 2; Toxic to aquatic life'.

The notified chemical is considered to be not chronically harmful to algae, but toxic with long lasting effects to fish and aquatic invertebrates. On the basis of its chronic toxicity to fish and aquatic invertebrates, and its lack of rapid degradability, the notified chemical is formally classified under the GHS as 'Chronic Category 2; Toxic to aquatic life with long-lasting effects'.

Reduced microbe efficiency to degrade organic matter was observed in test suspensions containing the notified chemical (2 mg/L). However, based on the results of activated sludge respiration inhibition testing, the median 3 hour inhibitory concentration (3 h IC50) for the notified chemical was found to be greater than 100 mg/L under the conditions of the test. Therefore, the notified chemical is considered to be not inhibitory to microbe respiration. See Appendix C for details of these studies.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the estimated chronic fish toxicity of the notified chemical and an assessment factor of 50. A more conservative assessment factor of 50 is appropriate in this case as although chronic endpoints (ChV = $(LOEC \times NOEC)^{½}$) for three trophic levels were reliably estimated by the aldehydes (mono) SAR (ECOSAR (v1.00); US EPA, 2009), these chronic endpoints are not no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (Fish)	0.14	mg/L
Assessment Factor	50	
PNEC:	2.80	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:	0.51	2.8	0.183
Q - Ocean:	0.05	2.8	0.018

The risk quotient for discharge of treated effluents containing the notified chemical to riverine environments indicates a relatively narrow safety margin as a result of the estimated chronic toxicity of this chemical. However, the notified chemical is unlikely to reach ecotoxicological significant concentrations in riverine environments based on its annual importation quantity and the partial removal of the chemical from waste water by sorption to sewage sludge. The notified chemical has a low potential for bioaccumulation and is unlikely to persist in surface waters. Therefore, at the maximum annual importation volume, the notified chemical is not expected to pose a risk to the environment based on the reported use in cosmetics and household products.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], with the following risk phrases:

Xn; R22: Harmful if swallowed
Xi; R43: May cause sensitisation by skin contact

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute oral toxicity		Harmful if swallowed
Skin sensitisation		May cause sensitisation by skin contact
Aquatic Environment	Acute Category 2	Toxic to aquatic life
	Chronic Category 2	Toxic to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern with maximum annual importation volume of up to 1 tonne, the notified chemical is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia, should consider the following hazard classification for the notified chemical:
  - Xn; R22: Harmful if swallowed
  - Xi; R43: May cause sensitisation by skin contact

- Use the risk phrase R22 for products/mixtures containing the notified chemical ≥25%
- Use the risk phrase R43 for products/mixtures containing the notified chemical ≥1%

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical at maximum of 0.1%:
  - Avoid contact with skin

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]

workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

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;

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of fine perfumes and other cosmetic and domestic products at 0.1%, or is likely to change 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -34.5 ± 7.0 ºC

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Test substance 1 was used for this determination.
Test Facility	SEPC (2000a)

Boiling Point 301ºC at 101.06 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Test substance 4 was used for this determination.
Test Facility	SPL (2000)

Density 1000 kg/m^3 at 20ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using an Oscillating densimeter at 20 ºC.
Test Facility	Process Safety & Analytical Development Laboratory-Firmenich 2010

Water Solubility 98×10^{-3} g/L ± 7×10^{-3} g/L at 20 ºC ± 0.5ºC

Method	OECD TG 105 Water Solubility/EC Directive 92/69/EEC A.6 Water Solubility. Flask Method. After a preliminary test, samples of the test substance (~0.1 g) were added to water (120 mL) in bottles protected from the light and shaken at ~30°C for 24 to 72 hours. After standing for 24 h at 20°C, the concentration of test substance in diluted aliquots were determined by HPLC(UV). The pH of each solution was measured.
Remarks	The saturated solutions were reported to be whitish in colour, and sample aliquots were not reported to be filtered before concentration analysis. Therefore, these results should be treated with caution. The pH was measured to be 7.39, 7.45 and 7.41 depending on whether the test solutions were shaken at 30°C for 24, 48 or 72 hours, respectively. The water solubility was not corrected for the purity of the test substance (81.9%).
Test Facility	CIT (2000a)

Partition Coefficient (n-octanol/water) log K_{OW} = 3.48 to 3.56 at 23 ± 1°C

Method	OECD TG 117 Partition Coefficient (n-octanol/water)/EC Directive 92/69/EEC A.8 Partition Coefficient. HPLC Method. The partition coefficient was determined by interpolation from a calibration curve constructed from six known standards (log K_{OW} range 2.1 to 4.5) in accordance with the guidelines above.
Remarks	The notified chemical eluted as two poorly resolved peaks.
Test Facility	CIT (2000b)

Flash Point >150ºC at 101.3 kPa, no flash point was observed.

Method	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	The determination was carried out using the closed cup equilibrium method. Test substance 1 was used for this determination. No flash point was observed up to 150ºC. From >150ºC, an orange flame was observed, (not considered as a flash point). Smoke was noticed at >170 ºC.
Test Facility	SEPC (2000b)

Autoignition Temperature 360 ± 5ºC

Method	Firmenich in house method, AIT instrument
Remarks	According to the norm DIN 51794 (ASTM2155)
Test Facility	Firmenich in house method

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (>80%, test substance 1)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/SD two groups of 3 males and one group of 3 females
Vehicle	Corn oil
Remarks - Method	The test substance was prepared in corn oil and administered by oral route (gavage)

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 males + 3 females	200	none
2	3 males	2000	Two in day1 & one in day 2

LD50	200< LD50 <2000 mg/kg bw
Signs of Toxicity	At 2000 mg/kg dose level, all males died between day 1 and day 2. Hypoactivity or sedation, dyspnea and lateral recumbency were observed prior to death. At 200 mg/kg dose level, no clinical signs and no mortality were observed in the animals.
Effects in Organs	The body weight gain of the animals given 200 mg/kg was not affected by treatment with the test substance. At necropsy, no apparent abnormalities were observed.
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	Centre International de Toxicologie (CIT, 2000)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical (>80%, test substance 1)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	None
Observation Period	72 hours after removal of dressing and then daily until reversibility of cutaneous reactions.
Type of Dressing	Semi-occlusive.

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	1.0	0.7	1.0	1	72 hour	1
Oedema	0.0	0.0	0.0	0	0 hour	-

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

Remarks - Results

A well–defined erythma (grade 2) was noted in all animals on day 1, and then a very slight erythma (grade 1) was observed up to day 3, 4, or 5.
Dryness of the skin was recorded in one animal between day 5 and day 7.

CONCLUSION

The notified chemical is slightly irritating to the skin and the effects were reversible.

TEST FACILITY

Centre International de Toxicologie (CIT, 2000)

B.3. Irritation – eye

TEST SUBSTANCE

Notified chemical (>80%, test substance 1)

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 males
Observation Period: 72 hours

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	0.0	0.3	0.3	1	24 hour	0
Conjunctiva: chemosis	0.0	0.0	0.3	1	24 hour	0
Conjunctiva: discharge	0.0	0.0	0.0	0	-	0
Corneal opacity	0.0	0.0	0.0	0	-	0
Iridial inflammation	0.0	0.0	0.0	0	-	0

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

Remarks - Results

Only very slight or slight (grade 1 or 2) conjunctival reactions (very slight or slight chemosis and very slight redness of the conjunctiva) were observed in all animals on day 1. They persisted for 24 hours in 2 animals.
No other ocular reactions were observed during the study.

CONCLUSION

The notified chemical is slightly irritating to the eye and the effects were reversible.

TEST FACILITY

Centre International de Toxicologie (CIT, 2000)

B.4. Skin sensitisation

TEST SUBSTANCE

Notified chemical (>80%, test substance 1)

METHOD

OECD TG 406 Skin Sensitisation – Maximisation method of Magnusson and Kligman.
EC Directive 96/54/EC B.6 Skin Sensitisation.

Species/Strain: Guinea pig/2 males and 2 females for the preliminary test

	15 males and 15 females for the main test
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 1%, 5%, 10%, 25%, 50% and 75% topical: 50% and 100%
MAIN STUDY	
Number of Animals	Test Group: 10 males and 10 females Control Group: 5 males and 5 females
INDUCTION PHASE	Induction Concentration: intradermal: 1% in corn oil topical: undiluted
Signs of Irritation	Signs of irritation were observed.
CHALLENGE PHASE	
1st challenge	topical: undiluted
Remarks - Method	Day 1: 3 pairs of intradermal injections were performed in the interscapular region of all animals: FCA diluted at 50% (v/v) with 0.9% NaCl (both control and test groups). Test substance at the chosen concentration in the chosen vehicle (treated group) or vehicle alone (control group). Test substance at the chosen concentration in a mixture FCA/0.9% NaCl 50/50 (v/v) (treated group) or vehicle at the concentration of 50% (w/v) in a mixture FCA/0.9% NaCl 50/50 (control group). Day 7: the same region received a topical application of sodium lauryl sulfate in vaseline (10% w/w) in order to induce local irritation. Day 8: the test substance (treated group) or the vehicle (control group) was applied topically to the same test site, which was then covered by an occlusive dressing for 48 hours. Day 22: all animals of the treated and control groups were challenged by a cutaneous application of the test substance to the right flank. The left flank served as control and received the vehicle only. Test substance and vehicle were maintained under an occlusive dressing for 24 hours. Skin reactions were evaluated approximately 24 and 48 hours after removal of the dressing.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge:*	
		24 h	*48 h*
Test Group	100%	13/20 5/20 Discrete erythma 8/20 Moderate erythma	15/20 7/20 Discrete erythma 8/20 Moderate erythma
Control Group	0%	0/10	1/10

Remarks - Results	No clinical signs or deaths were noted during the study. After challenge application, only a discrete erythema, associated with dryness of the skin, was observed at the 48 hours reading in 1/10 animals of the control group. In the treated group, a discrete erythema was noted in 5/20 animals at the 24-hour reading and in 7/20 animals at the 48-hour reading; A moderate erythema was observed in 8/20 animals at the 24-hour reading and in 8/20 animals at the 48-hour reading. At the 48-hour reading, dryness of the skin was observed in 14 animals and crusts were noted in 1/20 animal. The sensitivity of Dunkin-Hartley guinea pigs was checked to a positive control (Mercaptobenzothiazole) at 20% concentration. The positive control substance induced positive skin sensitisation reactions in 80% of guinea pigs.

CONCLUSION	There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Centre International de Toxicologie (CIT, 2000)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (>80%, test substance 2)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9-mix from livers of male Sprague-Dawley rats with aroclor 1254 at 500 mg/kg five days before S9 preparation.
Concentration Range in Main Test	a) With metabolic activation: 1.5 to 5000 µg/plate b) Without metabolic activation: 1.5 to 5000 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	Strains were treated with the test material using the Ames plate incorporation method at up to six dose levels, in triplicate, both with and without the addition of a rat liver homogenate metabolising system (10% liver S9 in standard co-factors).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	(in strain TA 100) ≥500	≥150	5000	Negative
Test 2	(in *E.coli* strain WP2uvrA-) non-toxic	≥150	5000	Negative
Present				
Test 1	(in strain TA 100) ≥500	≥150	5000	Negative
Test 2	(in *E.coli* strain WP2uvrA-) non-toxic	≥500	5000	Negative

Remarks - Results	All of the positive control chemicals used in the test induced marked increase in the frequency of revertant colonies, both with and without metabolic activation. The sensitivity of the assay and the efficacy of the S9-mix were validated. The test material caused a visible reduction in the growth of the bacterial lawn in all of the *Salmonella* tester strains, initially at 150 µg/plate, both with and without metabolic activation. The sensitivity of the *Salmonella* strains to the toxicity of the test material varied between strains and between exposures with or without S9-mix. No toxicity was observed in *E. coli* strain WP2uvrA-. The test material was tested up to either its toxic limit or the maximum recommended dose 5000 µg/plate, depending on bacterial strain type and presence or absence of S9-mix. Precipitate was observed at 5000 µg/plate, this did not prevent the scoring of revertant colonies. No significant increases in the frequency of revertant colonie were recorded for any of the bacterial strains with any dose of the test material, either with or without metabolic activation.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (2007)

B.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical (>80%, test substance 2)	
METHOD	Modified Buehler (1965) method. 3rd edition Hemisphere Publishing Corp., Marzulli and Maibach, 1987.	
Species/Strain	Guinea pig/ Hartley derived 2 males and 2 females for the preliminary test 15 males and 15 females for the main test	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 25%, 50%, 75% and 100%	
MAIN STUDY		
Number of Animals	Test Group: 10 males and 10 females	Control Group: 5 males and 5 females
INDUCTION PHASE	Induction Concentration: topical: 100%	
Signs of Irritation	No signs of irritation were observed.	
CHALLENGE PHASE		
1st challenge	topical: 100%	
Remarks - Method	25%, 50%, 75% and 100% concentrations were tested preliminary to determine the highest non-irritating and mildly irritating concentration of the test substance. The test material at each concentration was applied to a one inch square gauze patch which was then placed on the clipped back of each animal. The patches were left in place for 6 hours and then removed. The test sites were scored for erythema at 24, 48 and 72 hours post application. The mildly irritating concentration is defined as the lowest concentration which produces erythema no grater than a Buehler score of 2. The highest non-irritating concentration is defined as the concentration that induces responses in the 4 guinea pigs. <u>Induction phase:</u> one group of 20 guinea pigs was exposed to the test material group, and one group of 10 guinea pigs was exposed to Dinitrochlorobenzene (DNCB). All animals were clipped as described above prior to dosing. DNCB at 0.75% in 50% aqueous ethanol was used for positive control group. Test sites were evaluated for degree of erythema at 24 and 48 hours post application. This procedure was repeated at the total of three 6-hour exposures. After the last patch application, the animals remained untreated for two weeks. <u>Challenge:</u> After two week rest period, test group and positive group were challenged on naïve sites with 100% concentration of the test material. 0.3% concentration of DNCB was used for the positive control group. Skin evaluations were made at 24, 48 and 72 hours post application. <u>Naïve control challenge:</u> one group of 10 guinea pigs not previously exposed to the test material and one group of 10 guinea pigs not previously exposed to DNCB, were exposed to similar dose level of their respective materials and wrapped as above. These animals served as controls for irritation testing. Approximately 24, 48 and 72 hours following removal of patches (which remained in place for 6 hours) readings were taken for erythema.	

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge:*		
		24 h	*48 h*	*72 h*
Test Group	100%	1/20	0/20	0/20
Positive Control Group	0.3% (DNCB)	10/10	10/10	8/10

Remarks - Results

At challenge, one of twenty animals in the test material group had very faint patchy erythema, and 19 animals had no erythema.

In the naïve control group none of the 10 animals had erythema. At 24 hours after challenge dosing 6 of 10 animals had faint confluent erythema, and 4 had moderate erythema. At 48 hours, 8 animals had faint confluent erythema and 2 animals had moderate erythema. At 72 hours, 2 animals had very faint patchy erythema and 8 animals had faint confluent erythema.

In the naïve positive control group, 3 of 10 animals had very faint patchy erythema, and 7 animals had no erythema at 24 hours post challenge dosing. At 48 hours, 4 animals had very faint patchy erythema, and 6 animals had no erythema. There was no erythema noted at 72 hours post dosing.

CONCLUSION

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

TEST FACILITY

Celsis Laboratory Group (1999)

B.7. Skin sensitisation – human volunteers

TEST SUBSTANCE

Notified chemical (>80%, test substance 2)

METHOD

Human repeated insult patch test (HRIPT) - occlusive

Study Design

Induction Procedure: 9 consecutive applications of the test substance
Rest Period: 12-14 days
Challenge Procedure: Challenge phase initiated during the sixth week of the study, with identical patches applied to sites previously unexposed to the study material. These patches were removed by subjects after 24 hours and the sites graded after additional 24 hours and 48 hours periods, i.e. , 48 and 72 hours after application.

Study Group

Individuals:
18 years of age or older
free of any systemic or dermatologic disorder
uniformly colored skin

Vehicle

1.0% in Diethyl phthalate (DEP)

Remarks - Method

121 subjects between the ages of 19 and 74 were enrolled and 102 subjects completed the study.

RESULTS

Remarks - Results

Under the conditions employed in this study, there was no evidence of sensitisation to the test substance at 1.0% in Diethyl phthalate (DEP).

CONCLUSION

The notified chemical at 1% was non-sensitising under the conditions of the test.

TEST FACILITY

TKL Research, INC (1999)

B.8. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical (>80%, test substance 3)
METHOD	Occlusive human repeated insult patch test (HRIPT)
Study Design	Induction Procedure: 9 consecutive applications of the test substance Rest Period: 10-15 days Challenge Procedure: Challenge phase initiated during the sixth week of the study, with identical patches applied to sites previously unexposed to the study material. These patches were removed by subjects after 24 hours and the sites graded after additional 24 hours and 48 hours periods, i.e. , 48 and 72 hours after application.
Study Group	Individuals: 18 years of age or older free of any systemic or dermatologic disorder uniformly colored skin
Vehicle	5.0% in Diethyl phthalate (DEP)
Remarks - Method	110 subjects between the ages of 18 and 75 were enrolled and 103 subjects completed the study.
RESULTS	
Remarks - Results	There were no adverse events reported. Under the conditions employed in this study, there was no evidence of sensitisation to the test substance at 5.0% in Diethyl phthalate (DEP)
CONCLUSION	The notified chemical at 5% was non-sensitising under the conditions of the test.
TEST FACILITY	TKL Research, INC (1999)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD

Inoculum	Secondary effluent inoculum from a predominantly domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological oxygen demand (BOD)
Remarks - Method	In accordance with the guidelines above, the dissolved oxygen uptake of inoculated medium containing the test substance (2 mg/L) in completely full closed bottles stored in the dark was measured over 28 days. A reference control (sodium acetate, 2 mg/L) and a toxicity control (sodium acetate and test substance, 2 mg/L each) were run in parallel. Biodegradation was determined by measuring the oxygen depletion in the medium and expressed as a percentage of the theoretical oxygen demand (ThOD: 4.3 mg/L). Test conditions were: 19 to 26°C, pH 7.43 at the start of the test.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	66.3
14	0.7	14	71.6
21	1.1	21	74.2
28	2.6	28	87.5

Remarks - Results

The percentage degradation of the reference compound surpassed the pass levels of 60% by 14 days and the dissolved oxygen was ≥ 0.5 mg/L in the test suspension replicates during the test. Therefore, test is considered valid.

Whilst the temperature exceeded the limits recommended in the guideline (20 to 24°C) the deviations were only for short periods of time and were not used to determine the maximum and minimum temperature in the test room (usually 20 to 22°C).

The dissolved oxygen depletion in the inoculum blank exceeded the guideline limit of 1.5 mg O_2/L after 10 days. The same phenomenon was observed in test water without the inoculum and, therefore, the oxygen decrease was not due to a high quantity of organic matter in the inoculum. The difference between biodegradation values of test substance replicates slightly exceeded the recommended 20%, however as the biodegradation was very low, this was attributed to the limit of precision of the method and the low observed biodegradation test results. The deviation from protocol, as described above, were not considered to have compromised the validity of the study.

The toxicity control achieved 18% biodegradation, and as this is below the guideline limits of 25% degradation, the test substance is considered to have significantly reduced the efficiency to degrade organic matter in the test suspensions.

The test substance achieved <3% biodegradation over the course of the

	study and, therefore, under the conditions of the test, the test substance is not considered to be readily biodegradable.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	CIT (2000c)

C.2.1. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Effluent containing activated sludge from a predominantly domestic sewage treatment works
Exposure Period	3 hours
Concentration Range	Nominal: 1, 3.16, 10, 31.6 and 100 mg/L Actual: Not determined
Remarks – Method	In accordance with the guidelines above, inoculated media containing synthetic sewage feed and test substance at nominal concentrations of 1, 3.16, 10, 31.6 and 100 mg/L were evaluated for their effect on respiration rates of activated sewage sludge after 3 hours. Inoculated media containing synthetic sewage feed and reference material (3,5-dichlorophenol), at concentrations of 4, 12 and 16 mg/L, and inoculum controls were run in parallel. The inhibitory effects of the test substance and the reference substance on the respiration rates of activated sludge are expressed as percentages of the mean respiration rate of the controls. Test conditions were: 22°C, pH 6-8, 280 mg $CaCO_3$/L.
RESULTS	
IC50	>100 mg/L at 3 hours
NOEC	Not reported
Remarks – Results	As the difference between the two controls was below 15% and the IC50 of the reference substance (15 mg/L) was between 5 and 30 mg/L, the test was considered valid. Under the experimental conditions the 3 hour IC50 is >100 mg/L for activated sludge and the test substance is therefore considered as not harmful to micro-organisms in water treatment plants.
CONCLUSION	The notified chemical is not inhibitory to microbe respiration
TEST FACILITY	CIT (2000d)

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