File No: LTD/1565

February 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Cyclopentol

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 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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1565	Firmenich Limited	Cyclopentol	Yes	<1 tonne per annum	Component of cosmetic and household cleaning products

*ND = not determined

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 phrase:

R38 Irritating to skin.

and

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below.

	Hazard category	*Hazard statement*
Serious Eye Damage/Eye Irritation	Category 2A	Causes serious eye irritation
Skin Corrosion/Irritation	Category 2	Causes skin irritation
Aquatic Environment	Acute Category 3	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.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio, maximum annual importation volume 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

- Safe Work Australia, should consider the following health hazard classification for the notified chemical:
  - Xi: R38 Irritating to skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc. ≥20%: R38

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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical during reformulation processes:
  - Enclosed, automated processes, where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical during reformulation processes:
  - Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation processes:
  - Coveralls, impervious gloves, goggles

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

- 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.

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;
  - the concentration of the chemical exceeds or is intended to exceed 1.15% in fine fragrances, 2.5% in other cosmetic products and 5% in household cleaning products.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of cosmetic and household cleaning products 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.

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

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified chemical by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment, including the recommendations on safe use of the notified chemical, were carried out by NICNAS.

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, analytical data, degree of purity, impurities and additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, adsorption/desorption, flammability and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Low Volume Chemical (LVC) permit

NOTIFICATION IN OTHER COUNTRIES
USA (1996), Philippines (2000), Canada (2004), Switzerland (2006), South Korea (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Cyclopentol

MOLECULAR WEIGHT
<500 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 liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	<-20 °C	Measured

Boiling Point	218 ± 2 °C at 98.0 kPa	Measured
Density	893 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.00328 kPa at 25 °C	Estimated - mean VP of Antoine & Grain methods with user input of boiling point, 218 °C (US EPA, 2009)
Water Solubility	0.210 g/L at 25 °C	Measured
Hydrolysis as a Function of pH	<10% after 28 days (40 °C, pH 2-12)	Measured. Expected to be hydrolytically stable under environmental conditions (pH 4-9, 25 °C).
Partition Coefficient (n-octanol/water)	log P_{ow} = 3.68	Measured
Adsorption/Desorption	log K_{oc} = 2.55	Calculated (KOCWIN v2.00, from log Kow, US EPA, 2009). Expected to have medium mobility in soil.
Dissociation Constant	Not determined	Not expected to dissociate under environmental conditions (pH 4-9)
Flash Point	96 ± 2 °C (closed cup)	Measured. Classified as a C1 combustible liquid (NOHSC, 2001)
Flammability	Not determined	Based on the flash point, not classified as flammable (NTC, 2007)
Autoignition Temperature	>96 °C based on flash point	Not expected to autoignite under normal conditions
Explosive Properties	Predicted negative	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Predicted negative	Contains no functional groups that would 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.

Dangerous Goods classification
Based on the 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 will be imported into Australia as a component (≤5%) of compounded fragrances.

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
Firmenich Ltd

TRANSPORTATION AND PACKAGING
The fragrance preparations containing the notified chemical (at ≤5% concentration) will be imported in tightly closed lacquered drums, typically of 180 kg size, but also 100, 50, 25, 10 or 5 kg. They will be transported by

road from the wharf or airport of entry to the Firmenich Ltd warehouse for storage and then distributed to reformulation sites. The end-use products will be packaged in containers suitable for retail sale.

USE
The notified chemical is intended to be used as a component of fragrances for a variety of cosmetic and household cleaning products (proposed usage concentration: ≤1.15% concentration in fine fragrances, ≤2.5% in other cosmetic products and ≤5% in household cleaning products).

OPERATION DESCRIPTION
The procedures for incorporating the imported preparations (containing ≤5% notified chemical) into end-use products will likely vary depending on the nature of the cosmetic and personal care/household cleaning products 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 a fully enclosed environment, followed by automated filling of the reformulated end-use products into containers of various sizes.

The end-use products containing the notified chemical (at ≤5% concentration) may be used by consumers and professionals such as hairdressers, 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
Mixer	4	2
Drum Handling	4	2
Drum Cleaning	4	2
Maintenance	4	2
Quality Control	0.5	1
Packaging	4	2
Salon Workers	Unspecified	Unspecified
Cleaners	Unspecified	Unspecified

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified chemical, as a component of the imported preparations or end-use products (≤5%), only in the event of accidental rupture of containers.

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified chemical (at ≤5% 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 mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

Exposure to the notified chemical in end-use products (at ≤5% concentration) may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hairdressers, workers in beauty salons) or in the cleaning industry. Such professionals may use some personal protective equipment 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 (at ≤5% concentration) through the use of the household cleaning products and the rinse-off and leave-on cosmetic and personal care products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

6.2. Human Health Effects Assessment

The 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 >2000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, acute skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Human, skin sensitisation – RIPT (10%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	non genotoxic

Toxicokinetics, metabolism and distribution.
Based on the water solubility (0.210 g/L at 25 ºC), partition coefficient (log P_{ow} = 3.68) and the low molecular weight (<500 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption are expected to occur. The notified chemical may also be absorbed across the respiratory tract.

Acute toxicity.
The notified chemical was found to be of low acute toxicity via the oral and dermal routes in studies conducted in rats and rabbits, respectively.

Irritation and Sensitisation.
The notified chemical was determined to be irritating to the skin of rabbits, with very slight to well-defined erythema and oedema noted. Blanching of the skin was observed in a single animal during the observation period and desquamation was noted up to and including the final day of observation.

In an eye irritation study in rabbits, mild to moderate conjuctival irritation and corneal opacity were noted with all treated eyes appearing normal within 14 days. The scores did not warrant classification of the chemical as an eye irritant according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However the results of the study did warrant classification of the chemical under the GHS. In addition, the notifier has classified the chemical as R36: Irritating to eyes.

The notified chemical was not a skin sensitiser when tested in guinea pigs and in a human repeat insult patch study (at 10% concentration).

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

Mutagenicity.
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation assay and was not clastogenic in an in vitro mammalian chromosome aberration test.

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: R38 Irritating to skin.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation
Exposure of workers to the notified chemical (at ≤5% concentration) may occur during blending operations. While the notified chemical was found to be irritating to the eyes and skin, irritant effects are not expected at the proposed introduction and usage concentrations. In addition, measures to minimise exposure including the use of appropriate PPE are expected to be in place. Therefore, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

End-use
Cleaners and beauty care professionals will handle the notified chemical at ≤5% concentration, similar to public use. Therefore, the risk to workers who regularly use the notified chemical is expected to be of a similar or lesser extent than that experienced by members of the general public who use such products on a regular basis. For details of the public health risk assessment see section 6.3.2.

Based on the information available, the risk to workers associated with the use of the notified chemical at ≤1.15% in fine fragrances, ≤2.5% in other cosmetic products and ≤5% in household cleaning products, is not considered to be unreasonable.

6.3.2. Public Health
At the proposed usage concentration of the notified chemical of ≤1.15% in fine fragrances, ≤2.5% in other cosmetic products and ≤5% in household cleaning products, acute toxicity effects are not expected. The repeated dose toxicity effects of the notified chemical have not been determined. However exposure is expected to be limited by the low concentration of the notified chemical in end-use products.

Therefore the risk associated with use of the notified chemical at ≤1.15% in fine fragrances, ≤2.5% in other cosmetic products and ≤5% in household cleaning products, is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of fragrance preparations for local reformulation into a variety of consumer products (cosmetics, household products, fine fragrances). Release during reformulation in Australia is expected to arise from spills (0.1%), formulation equipment cleaning (no release estimate as cleaning water is recycled) and residues in import containers (0.1%). Accidental spills during transport or reformulation are expected to be collected with inert material and disposed of to landfill. Import containers will either be recycled or disposed of through an approved waste management facility. Therefore, up to 0.2% of the import volume is estimated to be released to landfill as a result of reformulation in Australia.

RELEASE OF CHEMICAL FROM USE
The notified chemical is expected to be released to sewers in domestic situations across Australia as a result of its use in cosmetic and household cleaning products, which are either washed off the hair and skin of consumers, or disposed of following cleaning activities.

RELEASE OF CHEMICAL FROM DISPOSAL
It is estimated that a maximum of 3% of the consumer products containing the notified chemical will remain in end-use containers. These will be disposed of through domestic garbage disposal and will enter landfill or be recycled.

7.1.2. Environmental Fate
Following its use in Australia, the majority of the notified chemical is expected to enter the sewer system. An estimated 89% of the notified chemical is predicted to be removed during sewage treatment plant processes (SimpleTreat; European Commission, 2003), with 73% removal by degradation and a further 16% removed through partitioning to sludge, before discharge to surface waters on a nationwide basis. The provided study indicates that the notified chemical is hydrolytically stable under the environmental conditions. The notified chemical is readily biodegradable (see Appendix C) and is thus considered rapidly degradable (United Nations 2009). Although the notified chemical has a high partition coefficient (log P_{ow} = 3.68) the notified chemical is not likely to bioaccumulate based on its predicted low bioconcentration factor (log BCF = 2.1, BCFBAF v3.00,

US EPA 2009). 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 moderately volatile (log H = 0.279 Pa/m^3/mol, SimpleTreat, European Commission, 2003) and may volatilise to air during use. The half-life of the notified chemical in air is calculated to be ≤7.4 h based on reactions with hydroxyl radicals (AOPWIN v1.29, US EPA, 2009). Therefore, in the event of release to atmosphere, the notified chemical is not expected to persist in the atmospheric compartment.

A proportion of notified chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill. Despite having moderate water solubility, notified chemical residues in landfill, soil and sludge are expected to have medium mobility based on its predicted soil adsorption coefficient (log K_{oc} = 2.55). The notified chemical is not expected to persist in the terrestrial compartment based on its ready biodegradability and is expected to degrade to form water and oxides of carbon.

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 will be released to sewer. Of this, an estimated 89% is predicted to be removed during sewage treatment plant (STP) processes (SimpleTreat, European Commission, 2003) 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	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	89%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.07	µg/L
PEC - Ocean:	0.01	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 0.969 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 0.006 mg/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 0.03 mg/kg and 0.06 mg/kg, respectively.

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 0.067 µg/L may potentially result in a soil concentration of approximately 0.4442 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 2.221 µg/kg and 4.442 µg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 13 mg/L	Harmful to fish
Daphnia Toxicity	48 h EC50 = 18 mg/L	Harmful to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 14 mg/L	Harmful to algae
	NOEC = 1.7 mg/L	Not harmful to algae with long lasting effects

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is harmful to fish, aquatic invertebrates and algae, and is formally classified as 'Acute Category 3: Harmful to aquatic life'. The notified chemical is not formally classified for long-term hazard under the GHS on the basis of its acute toxicity to aquatic biota, its rapid degradability and partition coefficient (log P_{ow} <4) in the absence of an experimentally derived BCF.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute fish toxicity of the notified chemical and an assessment factor of 100 as measured acute endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	13	mg/L
Assessment Factor	100	
PNEC:	130	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:	0.07	130	<0.001
Q - Ocean:	0.01	130	<0.001

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations based on its annual importation quantity and the partial removal of the chemical from waste water by degradation and sorption to sewage sludge. The notified chemical has a low potential for bioaccumulation and is unlikely to persist in surface waters, soil or air. Therefore, on the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in cosmetic and household cleaning 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 ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by placing a test tube containing the test substance in a dry ice/acetone bath until the temperature of the substance reached ~-20 ºC. The test substance did not show any indication of freezing.
Test Facility Firmenich (2005)

Boiling Point 218 ± 2 ºC at 98.0 kPa

Method OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Determined according to the Siwoloboff method.
Test Facility Firmenich (2005)

Density 893 kg/m^3 at 20 ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using an oscillating density metre.
Test Facility Firmenich (2005)

Water Solubility 210.4 mg/L at 25 ºC

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method/Column Elution Method
Test Facility Firmenich (2008a)

Hydrolysis as a Function of pH <10% after 28 days (40 ºC, pH 2-12)

Method In-house

pH	*T (ºC)*	*% hydrolysis after 28 days**
2	40	≤10
5	40	≤10
7	40	≤10
8.5	40	≤10
12	40	≤10

* Data points are approximated based on the provided graph

Remarks 0.001 M notified chemical in buffer solutions (types A, C, D, F and I: Reference Handbook of Chemistry and Physics) with 1% non-ionic surfactant. GC-FID determination at day 1, 2, 5, 8, 15 and 28.

Hydrolysis was less than 10% after 28 days storage at 40 ºC over the tested pH range (2-12), indicating the notified chemical is expected to be hydrolytically stable under environmental conditions (pH 4-9, 25 ºC).

Test Facility Firmenich (2011)

Partition Coefficient (n-octanol/water) log Pow = 3.68

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks HPLC Method.

Test Facility	Firmenich (2008a)

Flash Point 96 ± 2 ºC

Method	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Determined using a closed cup equilibrium method.
Test Facility	Firmenich (2005)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawley, 5M/5F
Vehicle	None
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	There were no mortalities observed.
LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Leberco-Celsis (1996a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rabbit/New Zealand White, 5M/5F
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	There were no mortalities observed.
LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Well-defined erythema was noted in all animals on day 1 which cleared by day 14 post-exposure. Well-defined oedema was noted in 4 animals and very slight oedema noted for a further 5 animals on day 1, which cleared by day 7 post-exposure.
Signs of Toxicity - Systemic	None
Effects in Organs	None
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Leberco-Celsis (1996b)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations
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	2	2	2	2	<14 days	0
Oedema	1	2	1	2	<7 days	0

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

Remarks - Results: Very slight to well defined erythema and oedema were noted. Blanching of the skin was noted in a single rabbit at the day 2, 3, 4 and 7 observations, while flaking of the skin was noted at the treated sites of all animals from day 4 onwards.

CONCLUSION: The notified chemical is irritating to the skin.

TEST FACILITY: Leberco-Celsis (1996c)

B.4. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Observation Period: 14 days
Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1.78	3	<14 days	0
Conjunctiva: chemosis	1.5	3	<14 days	0
Conjunctiva: discharge	1.61	3	<14 days	0
Corneal opacity	0.83	1	<7 days	0
Iridial inflammation	0.06	1	<4 days	0

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

Remarks - Results: Minimal to moderate conjunctival irritation and corneal opacity were noted in treated eyes. The treated eyes were normal after 14 days.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Leberco-Celsis (1996d)

B.5. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation - Magnusson and Kligman guinea pig maximisation test.
Species/Strain: Guinea pig/Dunkin Hartley
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 5%
topical: 100%
MAIN STUDY
Number of Animals: Test Group: 20F Control Group: 10F
INDUCTION PHASE: Induction Concentration:
intradermal: 5%
topical: 100%

Signs of Irritation	Following the intradermal and topical induction phases, moderate irritation at the induction sites was noted.
CHALLENGE PHASE	
1st challenge	topical: 100%
Remarks - Method	No significant protocol deviations. The vehicle was liquid paraffin. The test sites were treated with sodium lauryl sulfate prior to the topical induction phase.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	0	0
Control Group	100%	0	0

Remarks - Results	One test animal was killed in extremis following the topical induction and was found to have a prolapsed uterus. One control animal was found dead prior to challenge, with no abnormalities noted following a post-mortem examination. Following the challenge phase, no signs of skin reaction were noted in any of the remaining animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Toxicol (1995)

B.6. Skin sensitisation – human volunteers

TEST SUBSTANCE	Notified chemical (10% in vehicle)
METHOD	Repeat insult patch test with challenge
Study Design	Induction Procedure: Patches containing 0.3 mL test substance were applied to the backs of participants three times per week (Mondays, Wednesdays and Fridays) for a total of 9 applications. Patches were removed by the participants after 24 h and graded after an additional 24 h (or 48 h for patches applied on Fridays). Rest Period: 10-15 days Challenge Procedure: A patch was applied to a naïve site. Patches were removed by the participants after 24 h and the sites were graded 24 and 48 h post-patch removal.
Study Group	80F, 32M; age range 21-68 years
Vehicle	75% diethyl phthalate / 25% ethanol
Remarks - Method	Occluded. The test substance was applied on a 25mm Hilltop Chamber patch.
RESULTS	
Remarks - Results	101/112 subjects completed the study. 4/112 subjects were discontinued for failure to keep the scheduled visits, 6/112 voluntarily withdrew and 1/112 was discontinued for a protocol violation (exclusionary medication). No adverse events were noted in the study.
CONCLUSION	The test substance was non-sensitising under the conditions of the test.
TEST FACILITY	TKL (2009)

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, TA102
Metabolic Activation	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 5, 15, 50, 150, 500, 1500 and 5000 µg/plate b) Without metabolic activation: 5, 15, 50, 150, 500, 1500 and 5000 µg/plate
Vehicle	Dimethyl sulphoxide
Remarks - Method	A preliminary toxicity test (0-5000 µg/plate) was performed to determine the toxicity of the test material (TA100 only). Tests 1 and 2 were conducted on separate days using fresh cultures and test substance solutions. Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: N-ethyl-N'-nitro-N-nitrosoguanidine (TA100, TA1535), mitomycin C (TA102), 9-aminoacridine (TA1537) and 4-nitroquinoline-1-oxide (TA98); ii) with S9: 2-aminoanthracene (TA100, TA1535, TA1537), benzo(a)pyrene (TA98) and 1,8-Dihydroxyanthraquinone (TA102). Based on the results of tests 1 and 2 (see remarks below) a third confirmatory test was conducted using strain TA1535 (without S9).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥500	≥1500	>5000	Negative
Test 2		≥500	>5000	Negative
Present				
Test 1	≥1500	≥1500	>5000	Negative
Test 2		≥1500	>5000	Negative

Remarks - Results	In general, significant increases in the frequency of revertant colonies were not recorded, with or without metabolic activation. A statistically significant increase in the frequency of revertant colonies was observed using strain TA1535 (test 1) in the absence of metabolic activation, at concentrations of 50, 150 and 500 µg/plate, without a clear dose-response relationship. The absence of a genotoxic effect was confirmed in a confirmatory assay. The test substance caused a visible reduction in the growth of the bacterial background lawn, with and without metabolic activation. The positive controls gave satisfactory responses confirming the validity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2005)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Lymphocytes
Metabolic Activation	S9 fraction from phenobarbitone/β-naphthoflavone induced male rat liver
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations. Vehicle and positive controls (ethylmethane sulfonate without S9 and cyclophosphamide with S9) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10.5, 18.4, 32.2, 56.4*, 98.7*, 172.7*, 302.3, 529.0, 925.7, 1620.0	4 h	22 h
Test 2	3.2, 5.7, 9.9, 17.4, 30.5*, 53.3*, 93.3*, 163.3, 285.7, 500.0	22 h	22 h
Present			
Test 1	10.5, 18.4, 32.2, 56.4*, 98.7*, 172.7*, 302.3, 529.0, 925.7, 1620.0	4 h	22 h
Test 2	10.5, 18.4, 32.2, 56.4, 98.7*, 172.7*, 302.3*,529.0 ,925.7, 1620.0	4 h	22 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥302.3	>1620*	Negative
Test 2	≥93.3	>1620*	Negative
Present			
Test 1	≥302.3	>1620*	Negative
Test 2	≥529.0	>1620*	Negative

*Phase separation noted at the end of the treatment.

Remarks - Results	Phase separation was reported at the following concentrations: ≥925.7 µg/mL and ≥529 µg/mL in test 1 (with and without S9 mix) and ≥302.3 µg/mL in test 2 (with S9 mix). No statistically significant increase in the number of cells with aberrations was noted at any concentration, with and without metabolic activation. The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	RCC (2008)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 310 Ready Biodegradability - CO_2 in Sealed Vessel (Headspace Test).
Inoculum	Activated sewage sludge from a predominantly domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Total inorganic carbon (TIC) Method (a):acidification to pH <3
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

Notified chemical		*Sodium benzoate (reference substance)*		*Notified chemical and sodium benzoate (inhibition check)*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
3	0.89				
7	50.09				
10	59.02				
14	61.38	14	89.24	14	73.11
17	69.93				
21	74.05				
24	76.92				
28	78.56	28	93.67	28	87.03

Remarks - Results

The mean TIC in the blank control after 28 days was 1.77 mg C/L meeting the validation criteria of <3 mg C/L. The reference substance control (sodium benzoate) met the validation criteria of >60% by day 14 of incubation.

The notified chemical at 20 mg C/L was shown to be non-inhibitory to the activity of the inoculum, based on the results of the inhibition check and reference control at day 28.

The notified chemical attained 10% biodegradation between day 3-7, and reached the pass level of >60% theoretical maximum inorganic carbon production (ThIC) by day 14, meeting the 10 day window and demonstrating that the notified chemical is readily biodegradable.

CONCLUSION The notified chemical is readily biodegradable.

TEST FACILITY Firmenich (2008b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static Commission Regulation (EC) No 440/2008 C.1 Acute Toxicity for Fish – Semi-static.
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	125 mg $CaCO_3$/L
Analytical Monitoring	GC FID
Remarks – Method	After a range finding test, a definitive test was conducted in accordance with the guidelines above and in compliance with GLP standards and principles. No significant deviations to the test protocol were reported. As the test substance was determined to be a volatile substance, the test was performed in a closed system and the test vessels were aerated during the test (air from air-space bubbled back into test medium) to maintain dissolved oxygen concentrations. The test medium was renewed daily. Test conditions: 22-23ºC; pH 7.4-7.7; 7.9-8.4 mg O_2/L.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0	0	0	0	0
4.6	5.0	7	0	0	0	0	0
10	7.5	7	0	0	0[1]	0[1]	0[1]
22	23	7	7	-	-	-	-
46	55	7	7	-	-	-	-
100	110	7	7	-	-	-	-

[1] Abnormality observed for all 7 fish - apathy and/or fish mainly at the bottom of the test vessel.

LC50	13 mg/L at 96 hours (95% confidence limit: 7.5-23 mg/L).
NOEC	5.0 mg/L at 96 hours.
Remarks – Results	The measured concentration varied from 64-122% of the nominal concentration: therefore, the reported results are based on the measured concentration. At the lowest tested concentration of 5.0 mg/L, all fish survived until the end of the test and showed no visible abnormalities. Sub-lethal effects, including apathy and fish mainly at the bottom of the test vessel, were observed in all fish at a test concentration of 7.5 mg/L, but all fish survived. At test concentrations of 23 mg/L and above, 100% mortality was observed after 3 hours. Due to the steepness of the concentration-effect relationship the LC50 could not be calculated using typical statistical analysis such as probit analysis. Instead, the LC50 was calculated as the geometric mean of the two consecutive concentrations with 0 and 100% mortality, with these concentrations representing the 95% confidence limits. The LOEC was determined to be 7.5 mg/L and the NOEC was 5.0 mg/L.
CONCLUSION	The notified chemical is harmful to fish.
TEST FACILITY	Harlan (2009a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia sp*. Acute Immobilisation Test – Static. Commission Regulation (EC) No 440/2008 C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	GC FID
Remarks - Method	After a range finding test, a definitive test was conducted in accordance with the guidelines above and in compliance with GLP standards and principles. No significant deviations to the test protocol were reported. As the test substance was determined to be a volatile substance, the test was performed in a closed system. Test conditions: 20 ºC; pH 7.9-8.0; 8.1-8.9 mg O_2/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<LOQ	20	0	0
0.32	0.37	20	0	0
1.0	1.33	20	0	0
3.2	3.91	20	0	0
10	9.96	20	0	0
32	31.6	20	15	20
100	97.4	20	20	20

LC50	23 mg/L at 24 hours (95% confidence limit: 18-30 mg/L). 18 mg/L at 48 hours (95% confidence limit: 10-32 mg/L).
NOEC	10 mg/L at 48 hours
Remarks - Results	After 24 hours, no immobilisation was observed up to a test concentration of 10 mg/L. At 32 mg/L, 75% immobilisation was observed and at 100 mg/L, 100% immobilisation was observed. The EC50 and confidence interval after 24 hours was determined using probit analysis. After 48 hours, no immobilisation was observed up to a test concentration of 10 mg/L while 100% immobilisation occurred at 32 mg/L and above Due to the steepness of the concentration-effect relationship the EC50 could not be calculated using typical statistical analysis such as probit analysis. Instead, the LC50 was calculated as the geometric mean of the two consecutive concentrations with 0 and 100% mortality, with these concentrations representing the 95% confidence limits. The measured concentration varied from 93 and 142% of the nominal concentration. However, the reported results are based on nominal concentration. The geometric mean of the measured concentrations, at the start and end of the test, are reported in the results table above. It can be seen that the measured results at 1.0 and 3.2 mg/L overestimate the concentration by >20%. However, the measured concentrations over the range 10-100 mg/L, being of most relevance to the calculation of the test endpoints, vary from the nominal concentration by <20%. Noting the stated method of calculating the 48 h EC50, the use of nominal concentration for the determination of the test endpoint is acceptable.
CONCLUSION	The notified chemical is harmful to aquatic invertebrates

TEST FACILITY Harlan (2009b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Commission Regulation (EC) No 440/2008 C.3 Algal Inhibition Test.

Species *Pseudokirchneriella subcapitata*
Exposure Period 72 hours
Concentration Range Nominal: Control (0), 0.32, 1.0, 3.2, 10, 32 and 100 mg/L
Actual: <LOQ, 0.10, 0.21, 1.7, 6.6, 22 and 101 mg/L
Auxiliary Solvent None
Water Hardness 24 mg $CaCO_3$/L
Analytical Monitoring GC FID
Remarks - Method After a range finding test, a definitive test was conducted in accordance with the guidelines above and in compliance with GLP standards and principles. No significant deviations to the test protocol were reported. As the test substance was determined to be a volatile substance, the test was performed in a closed system. Test conditions: 23-24 ºC; pH 8.2-8.8.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
4.9	1.7	14.0	1.7
(95% confidence limits: 3.0-7.8)		(95% confidence limits: 11.3-17.5)	

Remarks - Results The validity criteria for the test were met.

The measured concentration varied from 63-107% of the nominal concentration at the beginning of the test and the measured concentration decreased to below the limit of quantification (LOQ=0.104 mg/L) for the 0.32 and 1.0 mg/L test solutions. Therefore, the reported results are based on the geometric mean of the measured concentrations.

The EC50 endpoints were calculated using Probit Analysis and NOECs were determined by comparison to the control using Dunnett's test.

CONCLUSION The notified chemical is harmful to algae

TEST FACILITY Harlan (2009c)

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