File No: LTD/1708

August 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

L-*gluco*-Octitol, 1,5-anhydro-6,8-dideoxy-, (7ξ)- (INCI name: Hydroxypropyl Tetrahydropyrantriol)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1708	L'Oreal Australia Pty Ltd	L-*gluco*-Octitol, 1,5-anhydro-6,8-dideoxy-, (7ξ)- (INCI name: Hydroxypropyl Tetrahydropyrantriol)	No	1 tonne per annum	Ingredient in cosmetics

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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 and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the neat notified chemical as introduced:
  - Avoid skin and eye contact

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

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 in body lotion is intended to exceed 3.5% or the concentration in other leave-on and rinse-off cosmetic and personal care products is intended to exceed 5%;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of cosmetics, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

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: other names, degree of purity, impurities, additives/adjuvants, use details, and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: dissociation constant and flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
France (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Mexoryl SBF

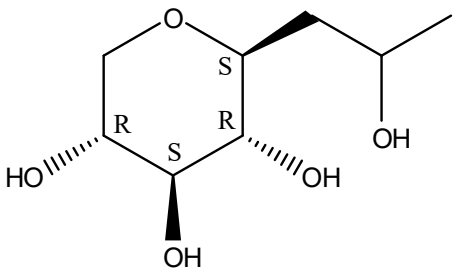
CAS NUMBER
439685-79-7

CHEMICAL NAME
L-*gluco*-Octitol, 1,5-anhydro-6,8-dideoxy-, (7ξ)-

OTHER NAME(S)
Hydroxypropyl Tetrahydropyrantriol (INCI name)

MOLECULAR FORMULA
$C_8H_{16}O_5$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
192.21 Da

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

3. COMPOSITION

DEGREE OF PURITY
70-90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: brown paste

Property	Value	Data Source/Justification
Melting Point/Freezing Point	63.8-181.4 °C	Measured
Boiling Point	284.9 °C at 101.3 kPa	Measured
Density	1,297 kg/m^3 at 20 °C	Measured
Vapour Pressure	1.7 x 10^{-9} kPa at 25 °C	Measured
Water Solubility	> 590 g/L at room temperature	Measured
Hydrolysis as a Function of pH	$t_{½}$ > 1 year at pH 4, 7, 9 and 25 °C	Measured
Partition Coefficient (n-octanol/water)	log Pow = -2.07 at room temperature	Measured
Surface Tension	66.2 ± 2.9 mN/m at 20 °C	Measured
Adsorption/Desorption	log K_{oc} = 1	Measured
Dissociation Constant	Not determined	Contains no readily dissociable functionalities
Flash Point	Not determined	Paste
Flammability	Not highly flammable	Measured
Autoignition Temperature	> 423 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported in finished cosmetic products at ≤ 5% concentration. The notified chemical may be introduced in the neat form for reformulation into cosmetic products in the future.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in finished products generally by sea in HDPE bottles or tubes in sizes up to 500 mL.

There is no information available in the case when the notified chemical is imported in the neat form.

USE
The notified chemical will be used as a component of cosmetic products such as body lotion (at ≤ 3.5% concentration) and other rinse-off and leave-on cosmetic and personal care products (at ≤ 5% concentration).

OPERATION DESCRIPTION
The notified chemical will be imported into Australia as part of cosmetic products (≤ 5% concentration), which will be sold to end-users in the same form in which they are imported. The notified chemical may at some point in the future be imported in neat form for formulation into cosmetic products.

The procedure for reformulation of the imported notified chemical (at 100% concentration) will likely vary depending on the nature of the cosmetic product formulated and may involve both automated and manual transfer steps. However, in general, it is expected that the formulation process will involve blending operations that will be highly automated and occur in a fully enclosed environment, followed by automated filling of the formulated products into containers of various sizes.

The finished products containing the notified chemical (at ≤ 5% concentration) may be used by consumers and professionals such as hairdressers and workers in beauty salons. Depending on the nature of the product, these could be applied in a number of ways, such as by hand, using an applicator or sprayed.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4	12
Professional compounder	8	12
Chemist	3	12
Packers (Dispensing and capping)	8	12
Store persons	4	12
End users	8	365

EXPOSURE DETAILS
Transport and storage workers may come in contact with the notified chemical as a neat chemical (at ≤ 100% concentration) or as a component of cosmetic products (at ≤ 5% concentration), only in the event of accidental rupture of containers.

During formulation, dermal, ocular and inhalation exposure to the notified chemical (at ≤ 100% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of 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 products to the clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of 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 through the use of body lotion (at ≤ 3.5% concentration) and other leave-on and rinse-off cosmetic and personal care products (at ≤ 5% concentration). The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

Data on typical use patterns of cosmetic and household cleaning product categories in which the notified chemical may be used are shown in the following tables (SCCS, 2010; Cadby *et al.*, 2002). For the purposes of the exposure assessment via the dermal route, Australian use patterns for the various product categories are assumed to be similar to those in Europe. In the absence of dermal absorption data, the default dermal absorption of 100% was assumed for calculation purposes (European Commission, 2003). Oral ingestion of lip products has not been estimated, given that 100% of the applied dose of lipstick/lip salve is considered to be systemically absorbed. For the inhalation exposure assessment (European Commission, 2003; SDA, 2005), an adult inhalation rate of 23 m^3/day (enHealth, 2004) was used and it was assumed that the bioavailability of the notified chemical via the inhalation route is 100%. An adult bodyweight of 60 kg has been used for calculation purposes.

Cosmetic products (dermal exposure):

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Body lotion	7820	3.5	1	4.562
Face cream	1540	5	1	1.283
Hand cream	2160	5	1	1.800
Deodorant (non-spray)	1500	5	1	1.250
Liquid foundation	510	5	1	0.425
Lipstick, lip salve	57	5	1	0.048
Eye shadow	20	5	1	0.017
Eye liner	5	5	1	0.004
Mascara	25	5	1	0.021
Hair styling products	4000	5	0.1	0.333
Shower gel	18670	5	0.01	0.156
Shampoo	10460	5	0.01	0.087
Hair conditioner	3920	5	0.01	0.033
Total				**10.018**

C = concentration; RF = retention factor.
Daily systemic exposure = Amount × C (%) × RF × dermal absorption (%)/body weight (60 kg)

Cosmetic products (inhalation exposure):

Product type	Frequency (use/day)	Amount (g/use)	C (%)	Inhalation rate (m^3/day)	Exposure duration (mins)	Airspace volume (m^3)	Daily systemic exposure (mg/kg bw/day)
Hair spray	2	10	5	23	15	2	1.997
Total							**1.997**

Daily systemic exposure = (Frequency × Amount × C × Inhalation rate × Exposure duration × bioavailability via the inhalation route)/(body weight × Airspace volume)

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above tables that contain the notified chemical. This would result in a combined internal dose of 12.015 mg/kg bw/day. It is acknowledged that inhalation exposure to the notified chemical from use of other cosmetic products (in addition to hair spray) may occur. However, it is considered that the combination of the conservative hair spray inhalation exposure assessment parameters, in particular assuming an airspace volume of 2 m^3, and the aggregate exposure from use of the dermally applied products, which assumes a conservative 100% absorption rate, is sufficiently protective to cover additional inhalation exposure to the notified chemical from use of other spray cosmetic products with lower exposure factors.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 29 days	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non-mutagenic

Toxicokinetics.
Based on the low molecular weight (192.21 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and skin is expected to occur; however, the hydrophilic nature of the notified chemical, as demonstrated by the partition coefficient (log Pow = -2.07) and the water solubility (590 g/L at room temperature), is expected to limit absorption. The notified chemical may be absorbed across the respiratory tract, however given the low vapour pressure (1.7×10^{-9} kPa at 25 °C) inhalation exposure will only occur in appreciable amounts when the notified chemical is aerosolised or heated.

Acute toxicity.
The notified chemical was of low acute oral and dermal toxicity in rats. No acute inhalation toxicity data were provided for the notified chemical.

Irritation.
The notified chemical was a slight skin and eye irritant to rabbits. Slight to moderate conjunctival redness and chemosis was observed in the eye irritation study but the notified chemical did not meet the criteria for classification as an eye irritant.

Sensitisation.
There was no evidence of skin sensitisation in a guinea pig maximisation test with the notified chemical.

Repeated dose toxicity.
In a 29-day repeat dose gavage study, rats (5/sex/dose) were treated at 0, 150, 450 or 1000 mg/kg bw/day. The NOAEL was established as 1000 mg/kg bw/day, based on the absence of treatment related adverse effects at any dose.

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

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Reformulation
Workers may experience dermal, ocular and inhalation exposure to the notified chemical (at 100% concentration) during formulation processes. This exposure may occur during handling of the drums, cleaning and/or maintenance of the equipment. At these facilities, exposure may also extend to compounders and laboratory staff involved in the formulation of the end products containing the notified chemical and the sampling and quality control testing of these products.

The use of enclosed, automated processes and PPE (impervious gloves, goggles, coveralls and face shield, if significant inhalation exposure is expected) is expected to be used during formulation processes. Based on the use of measures used to mitigate exposure and the overall low toxicity of the notified chemical, the risk to workers from use of the notified chemical is not considered to be unreasonable.

End-use
Workers involved in professions where the services provided involve the application of cosmetic products containing the notified chemical to clients (*e.g.*, hairdressers and beauty salon workers) may be exposed to the

notified chemical. The risk to these workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical (for details of the public health risk assessment, see Section 6.3.2.).

Such professionals may use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. For hairdressing salons, good ventilation would be recommended if hair spray is routinely used in a confined space. If PPE is used, the exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using the various cosmetic products containing the notified chemical. Based on the information available, the risk to workers associated with use of the notified chemical in body lotion (at ≤3.5% concentration) and other leave-on and rinse-off cosmetic and personal care products (at ≤5% concentration) is not considered to be unreasonable.

6.3.2. Public Health

At the proposed usage concentrations in body lotion (at ≤ 3.5% concentration) and other leave-on and rinse-off cosmetic and personal care products (at ≤ 5% concentration), skin and eye irritation effects are not expected.

The repeated dose toxicity potential for the notified chemical was estimated by calculation of a margin-of-exposure (MoE) using the worst case exposure scenario of 12.015 mg/kg bw/day (see Section 6.1.2.) from the use of multiple products. Using a NOAEL of 1000 mg/kg bw/day, which was derived from a 29-day repeated dose toxicity study with the notified chemical, the MoE was estimated to be 83. A MoE value ≥ 100 is normally considered acceptable to account for intra- and inter-species differences. However, in this case the MoE of 83 is considered acceptable based on the conservative nature of the cumulative exposure estimation for simultaneous users of all cosmetic products; the hydrophilic nature of the notified chemical that is expected to limit dermal absorption; the lack of toxicity observed at the NOAEL of 1000 mg/kg bw/day; and the low hazard profile of the notified chemical.

Overall, based on the available information, the risk to the public from use of the notified chemical in body lotion (at ≤ 3.5% concentration) and other leave-on and rinse-off cosmetic and personal care products (at ≤ 5% concentration) is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia as part of cosmetic products (≤ 5% concentration) or in neat form for formulation into cosmetic products. Environmental release during importation, transport and distribution may occur as a result of accidental breakage and spills. In the event of a spill, the notified chemical is expected to be contained and collected with an inert absorbent material and disposed of in accordance with local regulations.

The notified chemical may be reformulated in Australia into a variety of cosmetic products. The formulation process will involve blending operations that will be highly automated and is expected to occur in a fully enclosed environment. The process will be followed by automated filling of the formulated products into containers of various sizes. Typical wastes generated during reformulation that may contain the notified chemical include reformulation equipment washings, empty import containers and spilt materials. The wastes may be collected and released to sewers for the worst case scenario.

RELEASE OF CHEMICAL FROM USE

Formulated products containing the notified chemical are expected to be applied to skin and hair. It is expected that the majority of the annual import volume will be washed off the skin and hair and released to the sewer following consumer use.

RELEASE OF CHEMICAL FROM DISPOSAL

Expired product and residues of the notified chemical in the empty consumer containers (up to 3% of the annual import volume) are likely either to share the fate of the container and be disposed of to landfill, or be washed to sewer when containers are rinsed before recycling.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable based on the provided degradability test reports (up to 24% over 28 days). For the details of the environmental fate studies refer to Appendix C. It is not likely to be bioaccumulative given the high water solubility of > 590 g/L.

The majority of the notified chemical is expected to be disposed of to sewer following its use in cosmetic products. A small proportion of the notified chemical may be discharged to landfill as residues in empty containers. In sewage treatment plants (STPs), the notified chemical is expected to mainly remain in the water phase, due to its high water solubility, and be released to the surface water with the STP effluent. In landfill or in soil, the notified chemical is expected to have potential to leach. In water or landfill, the notified chemical is expected to degrade biotically and abiotically to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming complete release of the notified chemical nationwide to sewage systems and no removal in the STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4.0 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20.2 µg/kg and 40.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

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 > 100 mg/L	Not harmful
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful
Algal Toxicity	72 E_rC50 > 100 mg/L	Not harmful
Inhibition of Bacterial Respiration	IC50 > 1000 mg/L	Not harmful

Based on the above endpoints, the notified chemical is not considered to be harmful to aquatic organisms. Based on the toxicity to aquatic biota the notified chemical is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) on acute and chronic bases.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated for the notified chemical using the common lower limit of the endpoint (100 mg/L) for fish, alga and *Daphnia*.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LL50/EL50/E_rC50	> 100	mg/L
Assessment Factor	100	
PNEC:	>1,000	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.61	> 1000	< 0.001
Q - Ocean:	0.06	> 1000	< 0.001

The risk quotient (Q = PEC/PNEC) was calculated to be < 0.001.

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 63.8-181.4 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks Differential Scanning Calorimetry method. Melting of the test item occurred progressively over a temperature range.
Test Facility Defitraces (2006a)

Boiling Point 284.9 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks Differential Scanning Calorimetry method
Test Facility Defitraces (2006a)

Density 1,297 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks Stereopycnometer method
Test Facility Defitraces (2007a)

Vapour Pressure 1.7 x 10^{-9} kPa at 25 °C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks Vapour pressure balance method
Test Facility Safepharm (2007)

Water Solubility > 590 g/L at room temperature

Method OECD TG 105 Water Solubility
EC Directive 92/69/EEC, A.6 of 31 July 1992
Remarks Flask Method. Solution samples were analysed by Flow Injection Analysis with Mass Spectrometry detection. The solubility of the notified chemical in water was found to be >590 g/L (coefficient of variation = 2%) at room temperature.
Test Facility CIT (2006a)

Hydrolysis as a Function of pH $t_{½}$ > 1 year at pH 4-9, 25°C

Method Directive 92/69/EEC, C.7 of 31 July 1992

pH	*T (°C)*	*$t_{½}$*
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks The degradation of the notified chemical at pH 4, 7, 9 and 50°C indicates hydrolysis of less than 10% after 5 days. This is considered to be equivalent to $t_{½}$ > 1 year at 25°C.
Test Facility CIT (2007a)

Partition Coefficient (n-octanol/water) log Pow < - 2.07 at room temperature

Method OECD TG 107 Partition Coefficient (n-octanol/water)
Directive No. 92/69/EEC, A.8, 31 July 1992
Remarks Flask Method. The estimation was based on the individual solubilities of the test item in n-octanol and water. The water solubility of the notified chemical was previously found to be > 590 g/L. The solubility in n-octanol was found to be < 5 g/L. Therefore, a log P_{OW} of < -

2.07 was determined.

Test Facility CIT (2006b)

Surface Tension 66.2 ± 2.9 mN/m at 20 °C

Method OECD TG 115 Surface Tension of Aqueous Solutions.
EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks Concentration: 1 g/L in demineralised water
Test Facility Defitraces (2007b)

Adsorption/Desorption log K_{OC} = 1
– screening test

Method OECD Guideline No. 121, adopted on 22nd January 2001
Directive 2001/59/EEC, C.19, 6 July 2001
Remarks HPLC was performed on an analytical column packed with a cyanopropyl solid phase containing lipophilic and polar moieties. As the test item is not ionizable, a test was performed with methanol/buffer (55/45 v/v) at pH 6.4 as the mobile phase. As the retention time was close to the dead volume and below the retention time of acetanilide (log K_{OC} = 1.25), the adsorption coefficient was estimated by using a calculation method.
Test Facility CIT (2007a)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks The test substance melted and boiled in contact with the flame. No ignition or propagation was observed.
Test Facility Defitraces (2006b)

Autoignition Temperature > 423 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks No self-ignition temperature was observed up to 423 °C
Test Facility Defitraces (2007c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Limit Test
Species/Strain Rat/Sprague-Dawley
Vehicle Water
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0/3
2	3 F	2000	0/3

LD50 > 2000 mg/kg bw
Signs of Toxicity Piloerection was observed in three animals within the first 2 hours after dosing. A body weight loss was observed in one animal with lower than expected body weight gains in a further two animals, over the first week of the observation period.
Effects in Organs No gross abnormalities observed.

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

TEST FACILITY CIT (2006c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test
Species/Strain Rat/Sprague-Dawley
Vehicle Water used to moisten test substance.
Type of dressing Semi-occlusive
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0/5
2	5 F	2000	0/5

LD50 > 2000 mg/kg bw
Signs of Toxicity - Local None
Signs of Toxicity - Systemic None
Effects in Organs No gross abnormalities observed.

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

TEST FACILITY CIT (2007c)

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	Water used to moisten test substance.
Observation Period	72 hours
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	0	0.7	0	1	< 72 hours	0
Oedema	0	0	0	0	no effects	0

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

Remarks - Results	Very slight erythema (grade 1) was observed in one animal at the 1, 24 and 48 hour observations. All other animals were free from irritation.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY CIT (2006d)

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	3
Observation Period	72 hours
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			
Conjunctiva: redness	0.7	1.0	0	2	< 72 hours	0
Conjunctiva: chemosis	0.7	0.7	0.7	2	< 72 hours	0
Conjunctiva: discharge	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	no effects	0
Iridial inflammation	0	0	0	0	no effects	0

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

Remarks - Results	Slight (grade 1) to moderate (grade 2) conjunctival redness was observed in all three animals up to 48 hours, with slight to moderate chemosis observed in two animals over this time period. Slight to moderate conjunctival discharge was observed in all animals at the 1 hour observation point. All eyes were normal after 72 hours.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY CIT (2006e)

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/Hartley
PRELIMINARY STUDY	Concentration: intradermal: 10% and 5% (with and without Freund's complete adjuvant) topical: 25% and 10% (applied at induction and challenge sites)
Signs of Irritation	Slight irritation following 10% intradermal treatment, with more pronounced irritation when administered with FCA/0.9% NaCl (50:50 v/v). Slight irritation was observed at the induction (interscapular) site at 25%, but no irritation was observed at the challenge (flank) site.
MAIN STUDY	
Number of Animals	Test Group: 10/sex Control Group: 5/sex
INDUCTION PHASE	Induction Concentration: intradermal: 10% topical: 25%
Signs of Irritation	Marked local skin reactions (without necrosis) were observed at the intradermal injections sites from day 11 to 18, in both the control and test groups.
CHALLENGE PHASE	
1st challenge	topical: 25%
Remarks - Method	The vehicle used for the intradermal inductions was 0.9% NaCl with distilled water used as the vehicle for the topical induction and challenge. A concurrent positive control was not conducted. A positive control study conducted by the laboratory within the previous six months confirmed the sensitivity of the laboratory.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	25%	0/10	0/10
Control Group	25%	0/5	0/5

Remarks - Results	Bodyweight gains were decreased in a single male and female rat. There were no deaths or signs of systemic toxicity observed. There were no dermal reactions observed in the test and control groups exposed to the test substance at a concentration of 25%, indicating the lack of skin sensitisation potential at this concentration of the notified chemical.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	CIT (2006f)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage

Exposure Information	Total exposure days: 29 days Dose regimen: 7 days per week
Vehicle	Water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M/5F	0	0/10
low dose	5M/5F	150	0/10
mid dose	5M/5F	450	0/10
high dose	5M/5F	1000	0/10

Mortality
There were no mortalities during the study.

Clinical Observations
Clinical signs observed included dyspnea in one male treated at 1000 mg/kg bw/day, opacity of the right eye and reflux in single different females treated at 450 mg/kg bw/day, and loud breathing in one male treated at 150 mg/kg bw/day. These findings are not considered to be treatment related due to their isolated nature.

There were no treatment related findings in a functional observational battery conducted at the end of the treatment period.

There were no treatment related changes in absolute body weights, body weight gain or in food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no treatment related changes in haematology, clinical chemistry or urinalysis. A statistically significant increase in triglyceride levels in males treated at 1000 mg/kg bw/day were within the historical control range, thus were not considered to be related to treatment.

Effects in Organs
There were statistically significant increases in absolute and relative thymus weights in males treated at 1000 mg/kg bw/day but were not considered to be toxicologically significant in the absence of associated histopathological findings.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the lack of treatment related adverse effects.

TEST FACILITY CIT (2007d)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test – Plate incorporation procedure and pre-incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 0, 312.5, 625, 1250, 2500 and 5000 µg/plate b) Without metabolic activation: 0, 312.5, 625, 1250, 2500 and 5000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations. A preliminary cytotoxicity study was conducted at 10-5000 µg/plate in strains TA98, TA100 and TA 102 with and without metabolic activation.

The plate incorporation method was used for all plates, except for the second mutagenicity study in the presence of metabolic activation where the pre-incubation method was used.

Vehicle and positive controls were conducted in parallel with the test material in accordance with the testing guideline.

RESULTS

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

Remarks - Results

No statistically or biologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or 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

CIT (2006g)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Sewage sludge from the aeration tank of a sewage treatment plant that was aerated for 5 days
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The biotic degradation of the notified chemical was measured as the quantity of CO_2 evolved by its mineralisation over the test period
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP).

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
14	11.3	11	72.5
28	24.3	28	77.3

Remarks - Results	All the test validity criteria were met. The notified chemical was not considered to be readily biodegradable.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	CIT (2006h)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 310 Ready Biodegradability: CO_2 in sealed vessels (Headspace Test)
Inoculum	Activated sludge collected from Eye sewage treatment works (Suffolk, UK)
Exposure Period	28 days
Auxiliary Solvent	Not applied
Analytical Monitoring	The total inorganic carbon (TIC) content was determined. The biodegradation was expressed as a percentage of the theoretical amount of inorganic carbon (ThIC) based on the amount of test compound that was added initially.
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP). The inorganic carbon concentrations were determined by measuring the amount of carbon dioxide released by acidification of a sample using a sample loop (5.0 mL). To release carbon dioxide, phosphoric acid (400 µL, 5% v/v) was automatically injected, the sample was purged and the gas released was then concentrated by trapping. It was desorbed and carried to a non-dispersive infrared detector (NDIR) whose output was calibrated to directly display the concentration of inorganic carbon present in the sample. A solution of sodium carbonate was used as a calibration standard on each occasion of analysis.

RESULTS

Notified chemical		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	6.6	7	90.9
28	5.0	14	94.9

Remarks - Results: All the test validity criteria were met. The notified chemical was not considered to be readily biodegradable under the conditions of this test.

CONCLUSION: The notified chemical is not readily biodegradable

TEST FACILITY: HLS (2010)

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.
EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish Semi-static.

Species: *Danio rerio*
Exposure Period: 96 hours
Auxiliary Solvent: Not applied
Water Hardness: 139-143 mg $CaCO_3$/L
Analytical Monitoring: An aliquot of each sample was diluted (in duplicate) and analysed by Flow Injection Analysis with Mass Spectrometry detection. The actual test concentrations were determined from a calibration curve ranging from 0.05 to 2 mg/L.
Remarks – Method: The test was conducted following the test guideline and good laboratory practice (GLP).
Following a range finding test, a limit test was conducted at a loading rate of 100 mg/L. Test solutions were changed daily. Mortality and sub-lethal effects were recorded at 0, 2, 4, 24, 48, 72 and 96 hours.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
0	7	0	0	0	0
100	7	0	0	0	0

LC50: > 100 mg/L at 96 hours
NOEC: 100 mg/L at 96 hours
Remarks – Results: All the test validity criteria were met. Measured concentrations in the limit test solution were within ± 20% of the nominal value (100 mg/L) during the test, except for sampling times 24 and 96 hours which were below 80% (*i.e.* 67% and 75%, respectively). The study results were reported based on the nominal loading rate.
No mortality and sublethal effects were observed in the test. The notified chemical is not harmful to fish.

CONCLUSION: The notified chemical is not harmful to fish

TEST FACILITY: CIT (2008a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static test. EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - Static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not applied
Water Hardness	238-289 mg $CaCO_3$/L
Analytical Monitoring	An aliquot of each sample was diluted (in duplicate) and analysed by Flow Injection Analysis with Mass Spectrometry detection. The actual test concentrations were determined from a calibration curve ranging from 0.05 to 2 mg/L.
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP). Following a range finding test, a limit test was conducted at a loading rate of 100 mg/L. Observations were carried out at 0, 24 and 48 hours in order to determine the number of immobilised daphnids in each test solution.

RESULTS

Nominal Concentration (mg/L)	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
0	20	0	0
100	20	0	0

EC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	All the test validity criteria were met. Measured concentrations in the limit test solution were within ± 20% of the nominal value (100 mg/L) throughout the test. The study results therefore were based on the nominal loading rate. No immobilisation was observed in the test. The notified chemical is not harmful to *Daphnia*.
CONCLUSION	The notified chemical is not harmful to *Daphnia*
TEST FACILITY	CIT (2008b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	Not applied
Water Hardness	34 ± 17 mg $CaCO_3$/L
Analytical Monitoring	An aliquot of each sample was diluted (in duplicate) and analysed by Flow Injection Analysis with Mass Spectrometry detection. The actual test concentrations were determined from a calibration curve ranging from 0.05 to 2 mg/L.
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP).

RESULTS

Biomass		*Growth*	
E_bC50 *mg/L at 72 h*	*NOEC* *mg/L*	*E_rC50* *mg/L at 72 h*	*NOEC* *mg/L*
> 100	100	> 100	100

Remarks - Results: All the test validity criteria were met. Measured concentrations in the limit test solution were within ± 20% of the nominal value (100 mg/L) throughout the test. The study results therefore were based on the nominal loading rate. No significant inhibition of the algal growth was observed in the test. The notified chemical is not harmful to alga.

CONCLUSION: The notified chemical is not harmful to alga

TEST FACILITY: CIT (2008c)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum: Activated sludge

Exposure Period: 3 hours

Remarks – Method: The test was conducted following the test guideline and good laboratory practice (GLP).

RESULTS

IC50: > 1000 mg/L

NOEC: 1000 mg/L

Remarks – Results: All the test validity criteria were met. The study results were based on the nominal loading rate. No significant inhibition of the sludge micro-organisms was observed in the test. The notified chemical is not harmful to micro-organisms.

CONCLUSION: The notified chemical is not harmful to sludge micro-organisms

TEST FACILITY: CIT (2006i)

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