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August 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Siloxanes and Silicones, di-Ph, Ph (trimethylsilyl)oxy

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 and Energy.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2083	L'Oréal Australia Pty Ltd	Siloxanes and Silicones, di-Ph, Ph (trimethylsilyl)oxy	ND*	1 tonne per annum	Cosmetic ingredient

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the limited available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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
Based on the low hazard and 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 engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed and automated processes
  - Local exhaust ventilation
  - Adequate general ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during reformulation:
  - Impervious gloves
  - Protective clothing
  - Respiratory protection if inhalation exposure may occur

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

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

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

Emergency procedures

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

Disposal

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

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 use concentration of the notified chemical is intended to exceed 3% in aerosol products;

or

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

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

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
L'Oréal Australia Pty Ltd (ABN: 40 004 191 673)
Level 12, 564 St Kilda Rd
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 exempt from publication include: specific other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, use details, import volume, site of manufacture/reformulation and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physical and chemical properties, except for water solubility and partition coefficient.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Europe (2008)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Diphenylsiloxy phenyl trimethicone (INCI Name)

CAS NUMBER
352230-22-9

CHEMICAL NAME
Siloxanes and Silicones, di-Ph, Ph (trimethylsilyl)oxy

MOLECULAR WEIGHT
< 1,000 g/mol

ANALYTICAL DATA
Reference IR and GC, spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≥ 75%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear liquid

Property	*Value*	*Data Source/Justification*
Freezing Point	< -68 °C	Measured[#]
Boiling Point	268 – 342 °C at 101.3 kPa	Measured[#]
Density	992.9 kg/m^3 at 20 °C	Measured[#]
Vapour Pressure	6.8×10^{-5} kPa at 25 °C	Measured[#]
Water Solubility	< 0.00052 g/L at 20 °C	Measured

Property	*Value*	*Data Source/Justification*
Hydrolysis as a Function of pH	Not determined, due to low water solubility.	Expected to be hydrolysable by analogy with similar siloxanes (NICNAS, 2018)
Partition Coefficient (n-octanol/water)	log P_{ow} > 6	Calculated (QSAR)
Adsorption/Desorption	log K_{oc} > 6	Calculated (QSAR)
Dissociation Constant	Not determined	Contains no dissociable functionality
Flash Point	141 °C at 101.3 kPa	Measured[#]
Flammability	Combustible liquid *	Based on measured flash point
Autoignition Temperature	395 °C at 96.8 kPa	Measured[#]
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Based on *Australian Standard AS1940* definitions for combustible liquids.
[#] Data obtained from a REACH dossier on the notified chemical provided by the notifier (REACH, 2019)

DISCUSSION OF PROPERTIES
For 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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

The notified chemical has a flash point of 141 ºC which is greater than 93 °C but less than its boiling point (268 – 342 ºC). Based on *Australian Standard AS1940* definitions for combustible liquid, the notified chemical may be considered as a Class C2 combustible liquid.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of finished leave on and rinse off cosmetic products at concentrations of ≤ 30%. In the future the notified chemical may also be imported as a raw material for reformulation into finished cosmetic products.

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 or Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical (at concentrations of ≤ 30%) will be imported as a component of finished cosmetic products in end use containers suitable for retail sales (sizes from ≤ 500 mL). The cosmetic products containing the notified chemical may also be imported in bulk and repackaged locally into containers suitable for retail sales. In the future the notified chemical may also be imported as a raw material in 18 kg bags in 18 L boxes for reformulation into finished cosmetic products.

USE
The notified chemical will be used in leave on and rinse off cosmetic products including in aerosols at concentrations of ≤ 30%.

OPERATION DESCRIPTION

Introduction
The notified chemical will not be manufactured in Australia. The imported finished cosmetic products containing the notified chemical (at concentrations of ≤ 30%) will be introduced in ready to sale containers or in bulk to repackage for distribution to retail customers.

Reformulation
In the future, the notified chemical may be imported as a raw material. At the customer reformulation sites, procedures for incorporating the notified chemical into end use products will likely vary depending on the nature of the formulated products and may involve both automated and manual transfer steps. In general, it is expected that the products containing the notified chemical will be weighed and added to the mixing tank where mixing with additional additives will occur to form finished cosmetic products. Subsequently, automated filling of the reformulated products into containers of various sizes will occur. The blending and filling operations are expected to be typically automated with enclosed systems and adequate ventilation. During the reformation process, samples of products containing the notified chemical will be taken for quality control purposes.

End use
The finished cosmetic products containing the notified chemical at concentrations of ≤ 30% will be used by consumers and professionals such as beauticians and hairdressers. Depending on the nature of the products, applications may be by hand, spray or through the use of applicators.

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 & Capping)	8	12
Store persons	4	12
Professional end users	8	365

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the notified chemical (at concentrations of ≥ 75%) as a raw material or as a component of finished cosmetic products (at concentrations of ≤ 30%), only in the unlikely event of an accidental breach of import containers.

Reformulation
During reformulation, dermal, ocular and inhalation exposure of workers to the notified chemical (at concentrations of ≤ 100%) may occur during weighing, transfer, blending, quality control analysis, cleaning and maintenance of equipment. The use of engineering controls including local exhaust ventilation and enclosed systems, and the use of personal protective equipment (PPE) such as coveralls, goggles, impervious gloves and appropriate respiratory protection if required by workers is expected to minimise exposure to the notified chemical during reformulation.

End use
Exposure to the notified chemical in finished cosmetic products (at concentrations of ≤ 30%) may occur in professions where the services provided involve the application of cosmetic products to clients (i.e., hair and beauty salons). The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible. Such professionals may use PPE to minimise repeated exposure and good hygiene practices are

expected to be in place. If appropriate PPE is used, exposure of such workers to the notified chemical is expected to be similar or to a lesser extent of that experienced by consumers using the same products.

6.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified chemical at concentrations of ≤ 30% through daily use of cosmetic products. The principal route of exposure will be dermal, while ocular and inhalation exposures are also possible, particularly if products are applied by spray. Incidental ingestion of the products is also possible from facial use.

Dermal absorption

A dermal absorption rate of 10% was suggested by the introducer for the notified chemical based on its physico-chemical properties. Since the notified chemical is a UVCB with limited water solubility and an estimated log P_{ow} greater than 4, the value of 10% dermal absorption is considered reasonable (EFSA, 2017). A dermal absorption study conducted on an analogue chemical also indicated low dermal absorption (CIR 1986, exempt information).

Daily systemic exposure

Typical daily systemic exposure to the notified chemical when using different types of cosmetic products was calculated using 10% dermal absorption and 30% concentration of the notified chemical in all cosmetic products except in aerosol products. Exposure from aerosol products were calculated using a maximum of 3% concentration of the notified chemical. For the purposes of exposure assessment via the dermal route, Australian use patterns for various product categories are assumed to be similar to those in Europe (SCCS, 2012; Cadby et al., 2002; ACI, 2010; Loretz et al., 2006). For inhalation exposure estimation, a two-zone approach (Steiling et al., 2014; Rothe et al., 2011; Earnest, Jr, 2009) is used with assumptions of an adult air inhalation rate of 20 m^3/day (enHealth, 2012) and a conservative inhalation fraction of 50%. For calculation purposes, a lifetime average female body weight of 64 kg (enHealth, 2012) is used.

Based on typical daily systemic exposure calculations, considering the worst case scenario of a consumer exposed simultaneously to all typical cosmetic products containing the notified chemical (3% concentration in aerosol products and 30% concentration in other cosmetics), the combined internal dose of the notified chemical is estimated as 7.68 mg/kg bw/day. It is acknowledged that exposure to the notified chemical from use of other cosmetic products that are not listed may occur. However, the combination of the conservative exposure parameters and the aggregate exposure pattern from use of the typical cosmetic products used in the calculation is considered adequately protective for other cosmetic uses.

6.2. Human Health Effects Assessment

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

Endpoint	***Result and Assessment Conclusion***
Acute oral toxicity – rat	LD_{50} > 2,000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	LD_{50} > 2,000 mg/kg bw; low toxicity
Skin irritation – rabbit	slightly irritating
Eye irritation – rabbit	slightly irritating
Skin sensitisation – mouse local lymph node assay	no evidence of sensitisation
Repeat dose oral toxicity – rat, 28 days	NOAEL > 1,000 mg/kg bw/day*
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test	non genotoxic

* established by the study authors

Toxicokinetics, Metabolism and Distribution

No toxicokinetic data on the notified chemical were submitted. The notified chemical has very low water solubility (< 0.52 mg/L) and an estimated log P_{ow} of > 6 which is expected to limit the dermal absorption.

The notifier provided a cosmetic ingredient review (CIR) on an analogue chemical with molecular weight less than 500 g/mol. In a cited dermal absorption study, the analogue chemical was applied once daily over the entire surface of the back of 5 human male volunteers at a dose of 50 mg/kg bw (CIR, 1986, exempt information). The analogue chemical remained in contact with the skin for a period of 20 hours, after which time any excess material was removed by washing. Blood and urine samples were taken for analysis. There was no statistically

significant increases of the analogue chemical or its metabolite in blood or urine suggesting very low dermal absorption of the analogue chemical.

Acute Toxicity
Based on the study reports submitted, the notified chemical is of low acute toxicity via the oral and dermal routes of exposure in rats with LD_{50} > 2,000 mg/kg bw for both exposure routes.

No acute inhalation toxicity data were submitted for the notified chemical.

Irritation and Sensitisation
Based on results from eye and skin irritation studies conducted in rabbits, the notified chemical was considered to be slightly irritating. Application of the notified chemical to the skin resulted in mild signs of irritation including erythema. The noted effects were reversible and were no longer evident 72 hours after treatment.

Instillation of the notified chemical into the eye resulted in mild, early-onset and transient ocular changes such as reddening of the conjunctivae and sclerae, discharge and chemosis. These effects were reversible and were no longer evident 24 hours after treatment.

The notified chemical does not require hazard classification for skin or eye irritation under GHS criteria.

No evidence of skin sensitisation for the notified chemical was observed in an LLNA study. Slight skin irritation was observed at concentrations of 50 and 100%.

Repeated Dose Toxicity
In a 28 day repeated dose oral toxicity study, the notified chemical was administered to rats at dosages of 200, 600 and 1,000 mg/kg bw/day. Treatment related effects included decreased body weight gain in male rats of the high dose group and female rats of mid and high dose groups during week 2 and 3 of the study.

Treatment related increase in relative liver weights were observed in all treated rats. Small but statistically significant increase in liver/brain weight ratio was also noted in male rats in the mid dose group. The increase in liver weights was associated with dose-related hepatic centrilobular hypertrophy. However, no statistically significant changes in the liver enzyme levels were noted. Increased incidence of fatty liver (periportal to diffuse fat deposition) were noted in male rats in the high dose group and in female rats in all treated groups. Increased incidence of bile duct proliferation (minimal degree) were also noted in male rats in the mid dose group and in female rats in the low and mid dose groups. Minimal hypertrophic changes of the follicular epithelium in the thyroid gland were observed in some male rats in all treated groups.

Small but statistically significant changes were also observed for some blood chemistry parameters including total bilirubin, cholesterol, haemoglobin, calcium and potassium. All the changes observed in blood chemistry fell within the historical control range and hence were not considered adverse by the study authors.

The study authors established a no observed adverse effect level (NOAEL) of > 1,000 mg/kg bw/day considering that the observed effects were adaptive.

The study did not include a recovery period to determine if the observed liver effects were reversible. It is also noted that individual variations in data in control and treatment groups along with small sample size per group may have contributed to amplification of the weight changes observed.

Mutagenicity/Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation assay and not considered to be genotoxic in an *in vitro* chromosome aberration test using Chinese hamster lung cells.

Health Hazard Classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

At high concentrations, the notified chemical may cause slight irritation to the skin and eyes.

6.3.1. Occupational Health and Safety

Reformulation

Reformulation workers may come into contact with the notified chemical at up to 100% concentration. The main route of exposure is expected to be dermal but accidental ocular exposure is also possible. Safe work practices, engineering controls and use of PPE, including impervious gloves, coveralls and eye protection would reduce the risk of adverse health effects.

End use

Beauty care professionals will handle end use products containing the notified chemical at concentrations of ≤ 30%. As certain protective measures including PPE may be used by these professionals, the risk to the workers is expected to be of a similar or lesser extent than that experience by members of the public who use such products on a regular basis. For details of the public health risk assessment see Section 6.3.2.

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

6.3.2. Public Health

Members of the public may experience repeated exposure to the notified chemical through the use of cosmetic products (containing the notified chemical at concentrations of ≤ 30%). The main route of exposure is expected to be dermal with some potential for inhalation and for accidental ocular or oral exposure.

No irritation effects are expected at concentrations of ≤ 30%.

In a worst case scenario, repeated use of several cosmetics containing the notified chemical (at 3% concentration in aerosol products and 30% concentration in other cosmetics) may result in a systemic absorption of 7.68 mg/kg bw/day for an average female (see Section 6.1.2).

Inhalation toxicity of the notified chemical has not been determined. However, use of cosmetic products in powder form (compact powder and eye shadow) containing the notified chemical is not considered to generate inhalable dust due to the nature of the products. Use of aerosol deodorant and hairspray products containing the notified chemical may result in an internal dose of 0.1562 mg/kg bw/day for an average female (see Section 6.1.2). An analogue chemical at 3% concentration was evaluated for toxicity via the inhalation route in a repeated dose inhalation toxicity study in rats and no adverse effects were reported (CIR, 1986, exempt information).

Considering the high NOAEL established from the repeated dose toxicity study in rats (> 1,000 mg/kg bw/day), no adverse systemic effects are expected from repeated exposure to the chemical in cosmetic products at concentrations of ≤ 30%.

Based on the information available the notified chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. The notified chemical is a cosmetic ingredient and will be imported as a raw material for blending into finished cosmetic products or as a component of finished, imported cosmetic products in bulk for repackaging in Australia or packed in retail size containers. In general, the reformulation processes are expected to involve automated blending operations in an enclosed environment, followed by automated filling of the finished products into end use containers. Wastes containing the notified chemical generated during reformulation include equipment wash water, residues in empty import containers and spilt materials. These wastes will either be released to sewers or disposed of to landfill according to local

government regulations. Release of the notified chemical to the environment in the event of accidental spills or leaks during reformulation, storage and transport is expected to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical is expected to be released to sewers across Australia as a result of its use in in cosmetic products, which will be washed off the hair and skin of consumers.

RELEASE OF CHEMICAL FROM DISPOSAL
Residues of the notified chemical in empty import and end use containers are likely to either share the fate of the containers and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

The majority of the notified chemical will enter sewers and be subsequently treated at sewage treatment plants (STPs) following its use in cosmetic products available to the general public.

The notified chemical is expected to be efficiently removed from effluent in STPs by partitioning to sludge (80%) and volatilisation (9%; Struijs et al. 1991). After treatment at STPs, approximately 11% of the notified chemical is expected to be released to surface waters. Based on its slight water solubility (< 0.5 mg/L) and high partition coefficient (log P_{ow} > 6), when released to surface waters, the notified chemical is expected to partition approximately equally between water and sediment. The measured vapour pressure (6.8×10^{-5} kPa at 25 °C) indicates that the notified chemical is moderately volatile and will partition to air during its lifecycle, including during STP treatment. Based on its high adsorption/desorption coefficient (log K_{oc} > 6), notified chemical in the gas phase is expected to strongly adsorb to particulate matter which will eventually settle to soil and sediment. The notified chemical is therefore not expected to be persistent in air.

Based on the results of a ready biodegradability study, the notified chemical was demonstrated to be not readily biodegradable by microorganisms (0% in 28 days). For details of the environmental fate study, refer to Appendix C. The notified chemical is expected to be ultimately degradable through hydrolytic processes (in surface water, sediment) and soil-based abiotic degradation pathways by analogy with other siloxanes (NICNAS, 2018). The bioconcentration factor (BCF) has been modelled to be < 2,000 which indicates a low potential to accumulate in aquatic organisms.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) for a worst-case scenario has been calculated on the assumption that 100% of the annual import quantity of the notified chemical is released to the sewer over 365 days per year. It is also assumed under the worst-case scenario that there is no removal of the notified chemical by STP processes (volatilisation, partitioning to solids and biodegradation). The resulting PEC in receiving waters is reported in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	0.56	µg/L
PEC – Ocean:	0.06	µg/L

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	LL50 > 100 mg/L (WAF)	Not harmful to fish up to its limit of water solubility
Daphnia Toxicity	EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrates up to its limit of water solubility
Algal Toxicity	ErL50 > 100 mg/L (WAF)	Not harmful to algae up to its limit of water solubility
Inhibition of Bacterial Respiration	EC50 > 1,000 mg/L	Does not inhibit bacterial respiration up to its limit of water solubility

WAF = water accommodated fraction

Based on the above ecotoxicological endpoints for the notified chemical, it is not expected to be harmful to aquatic life up to the limit of its water solubility. Therefore, the notified chemical is not formally classified for either acute or chronic toxicity under the *Globally Harmonised System of Classification of Chemicals* (GHS; United Nations, 2009) due to a lack of aquatic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated as the notified chemical is not expected to be harmful to aquatic organisms up to its water solubility limit.

7.3. Environmental Risk Assessment

A Risk Quotient (PEC/PNEC) has not been calculated as the notified chemical is not expected to be harmful up to its water solubility limit. The notified chemical has a low potential for bioaccumulation but is predicted to be persistent in the environment until it is degraded by hydrolytic- or soil-based abiotic degradation mechanisms.

On the basis that the notified chemical is not toxic to aquatic life up to its solubility limit, it is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility < 0.00052 g/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Column Elution Method
Test Facility	Confidential (2004)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001)
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	Corn oil
Remarks – Method	No major deviations from the test guideline were reported.

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	Slightly ruffled fur was noted in 1 animal from each group at the 1 hour reading and persisted up to the 3 hour reading in the animal from group 1.
Effects in Organs	No abnormities were observed at necropsy
Remarks – Results	All animals showed expected body weight gain during the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	Confidential (2004)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity (1987)
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	None
Type of dressing	Semi-occlusive
Remarks – Method	No major deviations from the test guideline were reported. The test substance was used as supplied. A volume of 2.02 mL/kg bw of test substance, which factored in the density (0.992 g/cm^3) of the test substance, was used to obtain a dose of 2,000 mg/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	10 (5 M/5 F)	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	Slight crusts were noted in 1 female rat on Day 14 and 15 of the study. No clinical signs were observed in the other animals.
Signs of Toxicity – Systemic	No signs of systemic toxicity were observed
Effects in Organs	No abnormities were observed at necropsy
Remarks – Results	All animals had expected body weight gain during the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Confidential (2004)

B.3. Skin Irritation – Rabbit

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion (2002)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M and 2 F)
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	No major deviations from the test guideline were reported. The test substance was used as supplied. The duration of application was 4 hours.

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	0.33	0.33	0.67	0.67	48 h	0
Oedema	0	0	0	0	–	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 was noted in all animals at the 1 hour examination. Very slight erythema persisted in all animals at the 24 hour examination and was still present in 1 animal at the 48 hour observation. The noted effects were reversible and were no longer evident 72 hours after treatment. No other effects were observed on the treated skin of any animal. The notified chemical was not classified as an irritant under GHS.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Confidential (2004)

B.4. Eye Irritation – Rabbit

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion (2002)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M and 2 F)
Observation Period	72 hours
Remarks – Method	No major deviations from the test guideline were reported. Test substance was used as supplied.

RESULTS

Remarks – Results	Instillation of the test substance into the eyes of the test animals resulted in mild, early-onset and transient ocular changes seen at 1 hour examination including reddening of the conjunctivae and sclerae, discharge and chemosis. The observed effects were reversible and were no longer evident at 24 hours after treatment. No abnormal findings were observed in the cornea or iris of any animal at any of the examinations. No staining of the treated eyes by the test substance and no clinical signs were observed. The notified chemical is considered to be slightly irritating to the rabbit

eye based on the Kay and Calandra criteria for classification.

The notified chemical was not classified as an irritant under GHS.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Confidential (2004)

B.5. Skin Sensitisation – LLNA

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2002)

Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Acetone:olive oil (4:1 v/v)
Preliminary study	No
Positive control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
Remarks – Method	No major deviations from the test guideline were reported.

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
Test Substance			
0 (vehicle control)	4 F	760	–
25	4 F	749	1.0
50	4 F	1,555	2.0
100	4 F	1,853	2.4
*Positive Control**			
25	4 F	2,804	8.4

* Historical value from a positive control test carried out in the laboratory

Remarks – Results Positive controls were not included in parallel with the study. The validity of the test method was confirmed by a satisfactory result for the positive control conducted historically.

Slight ear swelling was observed in test animals exposed to 100% test substance on Day 2 of application. Slight ear erythema was observed in test animals exposed to 50% and 100% test substance on Day 3 of application. The effects persisted till the end of the study suggesting slight skin irritation.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY Confidential (2004)

B.6. Repeat Dose Oral Toxicity – Rat

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral)

Species/Strain	Rat/ HanBrl:WIST (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	Corn oil
Remarks – Method	No major deviations from the test guideline were reported. Dose levels

were decided based on a non-GLP 5 day range finding study in which the test substance was administered by gavage to 2 rats per group and sex. Treated animals showed no clinical signs.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	10 (5 F/5 M)	0	0/10
Low Dose	10 (5 F/5 M)	200	0/10
Mid Dose	10 (5 F/5 M)	600	0/10
High Dose	10 (5 F/5 M)	1,000	0/10

Mortality and Time to Death
All animals survived until scheduled necropsy

Clinical Observations
No test substance-related clinical signs were evident.

Statistically significant reduction in weight gain was observed in male rats from high dose group when measured on Day 8 and Day 15 of exposure with 19% and 18% reduction when compared to control, respectively. Significant reduction in body weight gain was also observed in female rats from mid dose (44% and high dose (48%) groups on Day 8 of exposure when compared to control.

The study authors considered these findings to be treatment related, but were minor and not of toxicological relevance.

There were no reported treatment related changes on food consumption in the test animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment related changes in haematology were observed.

Total bilirubin levels were significantly lower in treated female rats. The reduction noted was 23%, 30% and 40% for low, mid and high dose groups, respectively when compared to control. Whereas in male rats significant reduction was seen only in high dose group with 30% reduction when compared to control. Similarly significant increase in cholesterol levels were observed in female rats from all treatment groups with an increase of 60%, 72% and 58% in low, mid and high dose groups, respectively. No significant change in cholesterol levels were observed in treated male rats. Significant increase in phospholipid levels were observed in female rats from mid (40%) and high dose (39%) groups. In male rats in the mid to high dose groups a slightly lower glutamate dehydrogenase (GLDH) activity and in females in the high dose group slightly lower potassium and calcium levels were observed. The reductions in GLDH and potassium and calcium levels reached statistical significance when compared to respective controls for male and female rats.

The actual values of all the changes reported above fell within the normal historical control range and hence were considered to be not treatment related by the study authors.

Significantly lower albumin/globulin ratios (15%) were noted in female rats in the high dose group. However, the authors noted that there were no toxicologically relevant effects on the absolute levels of albumin or globulins, and considered these changes to be not treatment related.

No treatment related changes were noted during urinalysis.

Effects in Organs
Statistically significant increase in absolute and relative liver weights were observed in treated animals. Compared to control, the relative weight increases in male rats were 12%, 22% and 18% for low, mid and high dose groups, respectively. Relative weight increases in female rats were 23%, 29% and 43% for low, mid and high dose groups, respectively. Similarly liver to brain weight ratios were also increased however, the increase did not reach statistical significance in male rats from low and high dose groups.

No test substance related macroscopic findings were evident at necropsy.

Treatment related microscopic changes in liver and thyroid were observed in test animals. In liver, minimal to slight mostly centrilobular hepatocellular hypertrophy was observed in both sexes of all test groups. Increased incidence and/or severity (ranging from minimal to moderate degrees) of hepatic fatty change (periportal to diffuse fat deposition) was observed in male rats in the high dose group and in female rats in all dose groups. Increased incidence of bile duct proliferation was observed in male rats from mid dose group and female rats from low and mid dose groups.

Minimal hypertrophic changes of the follicular epithelium in the thyroid gland was observed in 4/5 males in the high dose group, 2/5 in the low dose group and 1/5 in the mid dose group.

Remarks – Results
The treatment related liver changes were reported as adaptive by the study authors. The thyroid finding was considered to be a secondary effect following hepatic hypertrophy and the authors concluded it was most likely due to increased metabolic turnover of thyroid hormones.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as > 1,000 mg/kg bw/day by the study authors.

TEST FACILITY Confidential (2004)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997)
Plate incorporation procedure and pre incubation procedure

Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA	
Metabolic Activation System	S9 mix from phenobarbitone (PB) and β-naphthoflavone (βNF) induced rat liver	
Concentration Range in Main Test	a) With metabolic activation:	33 – 5,000 µg/plate
	b) Without metabolic activation:	33 – 5,000 µg/plate
Vehicle	Ethanol	
Remarks – Method	No major deviations from the test guideline were reported.	

Concentrations for main test were chosen based on the plate incorporation method conducted on TA100, TA1535 and WP2*uvr*A (base-pair substitution type) and on TA98 and TA1537 (frameshift type) results.

As the results of Test 1 were negative, treatments in the presence of S9 mix in Test 2 included a pre-incubation step.

Tests with vehicle and culture medium controls and positive controls were run concurrently. Positive controls were: *(a)* With metabolic activation: 2-aminoanthracene (TA1537, TA1535, TA100, TA98 and WP2*uvr*A); *(b)* Without metabolic activation: sodium azide (TA1535, TA100), methyl methane sulfonate (WP2*uvr*A); 4-nitro-o-phenylene-diamine (TA1537, TA98)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	–	5,000	Negative
Test 2	–	> 5,000	≥ 2,500	Negative
Present				
Test 1	> 5,000	–	5,000	Negative

Test 2	–	> 5,000	≥ 1,000	Negative

Remarks – Results: The test substance did not result in an increase of more than twice the number of revertant colonies in comparison to the negative control. In addition, no dose-related response was observed in any strains of base-pair substitution type or frame-shift type, with or without metabolic activation.

The positive and negative controls provided a satisfactory response confirming the validity of the test system.

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

TEST FACILITY: Confidential (2004)

B.8. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Directive 2000/32/EC B.10 Mutagenicity – *In vitro* Mammalian Chromosome Aberration Test

Cell Type/Cell Line: Chinese hamster lung cells (CHL) (V79 cell line)
Metabolic Activation System: Phenobarbitone (PB) and β-naphthoflavone (βNF) induced rat liver S9 mix
Vehicle: Ethanol
Remarks – Method: Ethylmethane sulphonate (EMS) and cyclophosphamide (CPA) were used as positive controls. The vehicle and culture medium were used as the negative controls.

No major deviations from the test guideline were reported.

Metabolic Activation	*Test Substance Concentration (μL/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.025*, 0.050*, 0.100*, 0.150*, 0.200, 0.300	4 h	14 h
Test 2	0.006*, 0.013*, 0.025*, 0.050*, 0.100*, 0.150*, 0.200	18 h	18 h
Test 3	0.013, 0.025, 0.050*, 0.100	28 h	28 h
Present			
Test 1	0.003, 0.006, 0.013*, 0.025, 0.050*, 0.100*, 0.200	4 h	14 h
Test 2 **	0.040*, 0.080*, 0.160*, 0.310, 0.630, 1.250, 2.500, 5.000	4 h	24 h

* Cultures selected for metaphase analysis.
** Test was repeated due to missing test substance precipitation.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	–	> 0.150	≥ 0.150	Negative
Test 2	–	> 0.150	–	Negative
Test 3	–	> 0.050	–	Negative
Present				
Test 1	–	> 0.100	≥ 0.100	Negative
Test 2	–	> 0.160	≥ 0.080	Negative

Remarks – Results: Toxic effects indicated by reduced cell numbers of below 50% of control or poor metaphase quality were observed after 18 hours continuous

	treatment in Test 2 in the absence of metabolic activation. In the other tests, reduced cell numbers and/or mitotic indices indicating cytotoxicity were not observed at the test substance concentrations evaluated. The test substance did not induce any statistically significant increases in the frequency of cells with chromosome aberrations either in the absence or presence of metabolic activation. The positive and negative (vehicle) controls provided a satisfactory response confirming the validity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster lung cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Confidential (2004)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test (1992)
Inoculum	Aerobic activated sludge from domestic sewage treatment plant (STP)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD
Remarks – Method	The test substance was directly weighed into the test flasks. Test solutions were prepared by adding activated sludge and water to the solid test substance. The nominal concentrations of the test substance and inoculum, at the start of the experiment, were 100 mg/L and 30 mg (dry weight)/L respectively. A positive control and a toxicity control were prepared by adding a stock solution of the reference compound (sodium benzoate) directly to the test medium.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	1	0
14	0	14	87
28	0	28	85

Remarks – Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation after 14 days indicating that the test substance had no inhibitory effect on the activity of sludge microorganisms.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	Confidential (2004)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static (1992)
Species	*Brachydanio rerio* (zebra fish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	228 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	A limit test was performed using a water accommodated fraction (WAF) of the test substance based on the results of a range finding test. The WAF (loading rate 100 mg/L) was prepared by dispersing the test substance in water and stirring for three hours. Extended stirring was avoided because components of the test substance are not stable in water. The dispersion was filtered through a 0.45 µm membrane filter and used directly as the test medium. Nominal concentrations (at 0 hours) are reported (instead of a measured concentrations) in accordance with international guidelines for WAFs (OECD, 2019). Temperature was maintained at 21 °C.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	< 0.1	7	0	0	0	0	0

LL50	> 100 mg/L at 96 hours
NOELR	100 mg/L at 96 hours
Remarks – Results	All validity criteria were satisfied. The dissolved oxygen concentration in the test solution during the test was ≥ 8.0 mg/L at 21 °C (≥ 89% air saturation, USGS, 2011). No abnormalities or mortality was observed in any of the fish up to 96 hours.

CONCLUSION The test substance is not harmful to fish up to its water solubility limit.

TEST FACILITY Confidential (2004)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static (1984)

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	A limit test was performed using a water accommodated fraction (WAF) of the test substance based on the results of a range finding test. The WAF (loading rate 100 mg/L) was prepared by dispersing the test substance in water and stirring for three hours. Extended stirring was avoided because components of the test substance are not stable in water. The dispersion was filtered through a 0.45 µm membrane filter and used directly as the test medium. Nominal concentrations (at 0 hours) are reported (instead of a measured concentrations) in accordance with international guidelines for WAFs (OECD, 2019). Temperature was maintained at 20 – 21 °C. A positive control was also run as a separate test using potassium dichromate as the reference item.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
100	< 0.7	20	0	0

EL50	> 100 mg/L at 48 hours
NOELR	100 mg/L at 48 hours
Remarks – Results	All validity criteria were satisfied. The 48 hour EC50 for the positive control experiment was 0.83 mg/L which is within the historical range of the laboratory. No adverse effects were observed in any of the daphnids in the control and test solutions. The pH values of the test solutions ranged from 7.7 – 7.8. The dissolved oxygen concentration in the test and control solutions was ≥ 8.2 mg/L at 21 °C (≥ 89% air saturation, USGS, 2011).

CONCLUSION The test substance is not harmful to aquatic invertebrates up to its water solubility limit.

TEST FACILITY Confidential (2004)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test (1984)
Species *Scenedesmus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal: 100 mg/L
Auxiliary Solvent None
Water Hardness 24 mg $CaCO_3$/L
Analytical Monitoring GC, Electronic Particle Counter
Remarks – Method A limit test was performed using a water accommodated fraction (WAF) of the test substance based on the results of a range finding test. The WAF (loading rate 100 mg/L) was prepared by dispersing the solid test item in water and stirring for three hours. Extended stirring was avoided because components of the test item are not stable in water. The dispersion was filtered through a 0.45 µm membrane filter and used directly as the test medium. Nominal concentrations (at 0 hours) are reported (instead of a measured concentrations) in accordance with international guidelines for WAFs (OECD, 2019). A positive control experiment was performed separately using potassium dichromate as the reference item. Temperature was maintained at 23 (± 1) °C.

RESULTS

Biomass		*Growth*	
EyL50 (mg/L WAF at 72 h)	*NOEL (mg/L WAF)*	*ErL50 (mg/L WAF at 72 h)*	*NOEL (mg/L WAF)*
> 100	100	> 100	100

Remarks – Results All validity criteria were satisfied. The cell concentration of the control cultures increased by a factor of 81 after 72 hours. The 72 hour ErC50 for the positive control was 0.69 mg/L which is within the historical range of the laboratory.

CONCLUSION The test substance is not harmful to algae up to its water solubility limit.

TEST FACILITY Confidential (2004)

C.2.4. Inhibition of Microbial Activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test (1984)
Inoculum Activated Sludge
Exposure Period 3 hours
Concentration Range Nominal: 10, 32, 100, 320 and 1,000 mg/L
Remarks – Method Test media were prepared by combining synthetic sewage, activated sewage sludge and the test substance which had been separately dispersed in water by intense stirring. Suspended test substance was observed in all of the test samples. The concentration of the inoculum was 1.6 g dry material per litre of test medium. Temperature was held at 19 °C. A positive control experiment was performed separately using 3,5-dichlorophenol as the reference item at concentrations of 5, 16 and 50 mg/L. All test media and controls were continuously aerated with compressed air at a flow of one litre per minute during the three hour period before BOD measurements were taken.

RESULTS	
NOEC	1,000 mg/L at 3 hours
Remarks – Results	All validity criteria were satisfied. The three hour EC50 for the positive control was 10 mg/L. The coefficient of variation of oxygen uptake in the control vessels was 6% and the specific respiration rate of the controls was 34 mg oxygen per gram dry weight of sludge per hour. The pH values of the test solutions ranged from 7.3 – 8.3. No significant effect on respiration was observed in any of the test samples.
CONCLUSION	The test substance had no inhibitory effect on bacterial respiration
TEST FACILITY	Confidential (2004)

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