File No.: LTD/2109

February 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

2-Propenamide, 3-(1,3-benzodioxol-5-yl)-*N*,*N*-diphenyl-, (2*E*)-

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 Agriculture, Water and the Environment.

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/2109	Colgate-Palmolive Pty Ltd	2-Propenamide, 3-(1,3-benzodioxol-5-yl)-*N*,*N*-diphenyl-, (2*E*)-	ND*	≤ 1 tonne per annum	Cosmetic ingredient (oral and lip products)

*ND = not determined

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 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
On the basis of the low hazard 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 engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed/automated processes
  - Local exhaust ventilation

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

- 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:
  - Safety glasses or goggles
  - 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 final use concentration of the notified chemical exceeds 0.5% in lip and oral care cosmetic products;
- further information becomes available on bacterial respiration in sewage sludge;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a cosmetic ingredient in lip and oral care products, 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 and products containing the notified chemical provided by the notifier were 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)
Colgate-Palmolive Pty Ltd (ABN: 79 002 792 163)
Level 14, 345 George Street
SYDNEY NSW 2000

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, analytical data, purity, and impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for hydrolysis as a function of pH, dissociation constant, flash point, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
European Union (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
2-Propenamide, 3-(1,3-benzodioxol-5-yl)-*N*,*N*-diphenyl-, (2*E*)-

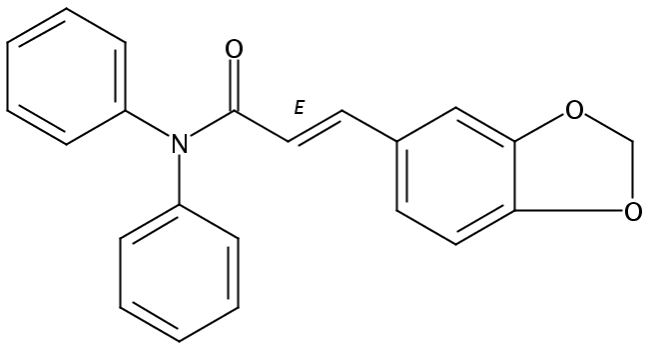
CAS NUMBER
1309389-73-8

CHEMICAL NAME
2-Propenamide, 3-(1,3-benzodioxol-5-yl)-*N*,*N*-diphenyl-, (2*E*)-

OTHER NAME
(*E*)-3-Benzo[1,3] dioxol-5-yl-*N*,*N*-diphenyl-2-propenamide

MOLECULAR FORMULA
$C_{22}H_{17}NO_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
343.38 g/mol

ANALYTICAL DATA
Reference NMR, FTIR, GC-MS, UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White to yellow solid powder

Property	*Value*	*Data Source/Justification*
Melting Point	146.4 °C	Measured
Boiling Point	Decomposes without boiling at 330 °C	Measured
Density	1,287 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.8 x 10^{-14} kPa at 20 °C 1.3 x 10^{-13} kPa at 25 °C 2.7 x 10^{-11} kPa at 50 °C	Measured
Water Solubility	1.25 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality but expected to be stable in the environmental pH 4-9
Partition Coefficient (n-octanol/water)	log Pow = 3.4 at 20 °C	Measured
Adsorption/Desorption	log K_{oc} = 3.2	QSAR (US EPA, 2012)
Dissociation Constant	Not determined	Does not contain dissociable functionality
Particle Size	D_{10} = 5.1 µm D_{50} = 27.5 µm D_{90} = 142.0 µm Inhalable fraction (< 100 µm): < 90% Respirable fraction (< 10 µm): < 25%	Measured
Flammability	Not flammable	Measured
Autoignition Temperature	Not self-heating	SDS
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

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.

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 into Australia as a component of finished cosmetic products at ≤ 0.5% concentration. In the future the notified chemical may also be imported neat as a solid powder 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 and Melbourne

TRANSPORTATION AND PACKAGING
The finished products containing the notified chemical at ≤ 0.5% concentration will be imported in containers suitable for retail sale (i.e. ≤ 750 mL mainly plastic (HDPE) bottles or tubes) and transported by road or rail for distribution to customers and retailers.

In the future the notified chemical may also be imported neat in 180 kg steel drums for reformulation into finished cosmetic products.

USE
The notified chemical will be used as a component of lip and oral care cosmetic products (including toothpaste, mouthwash and lipstick) at ≤ 0.5% concentration.

OPERATION DESCRIPTION

Reformulation
The 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. However, in general, it is expected that for the reformulation processes, the notified chemical will be weighed and added to the mixing tank where it will be blended with additional additives to form the finished cosmetic products. This will be followed by automated filling of the reformulated products into containers of various sizes. The blending operations are expected to be highly automated and use closed systems and/or adequate ventilation. During the reformulation process, samples of the notified chemical and the finished end-use products will be taken for quality control testing.

End-use
Finished cosmetic products containing the notified chemical at ≤ 0.5% concentration will be used by consumers and professionals such as dentists.

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
Compounder	8	12
Chemist	3	12
Packers	8	12
Store persons	4	12
Professional end users (dentists, etc.)	8	365

EXPOSURE DETAILS

Transport and storage
Transport, distribution and warehouse workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident.

Reformulation
During reformulation, dermal, ocular and inhalation exposure to the neat notified chemical at ≤ 100% concentration may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. Given the low vapour pressure (1.3×10^{-13} kPa at 25 ºC) of the notified chemical, inhalation exposure to the notified chemical is not expected unless aerosols are formed.

The notifier states that exposure is expected to be minimised through the use of local ventilation and/or enclosed systems, and through the use of personal protective equipment (PPE) such as protective clothing, goggles, impervious gloves and respiratory protection (in cases where there is inadequate ventilation).

End-use
Exposure to the notified chemical in end-use products at ≤ 0.5% concentration may occur in professions where the services provided involve the application of oral care cosmetic products to clients (e.g. dentists). The principal route of exposure will be dermal. Such professionals are expected to use PPE, including gloves and coveralls, to minimise repeated exposure, and good hygiene practices are expected to be in place.

6.1.2. Public Exposure
There will be widespread and repeated exposure of the public to the notified chemical at ≤ 0.5% concentration in lip and oral care cosmetic products. The principal route of exposure will be oral, while accidental dermal and ocular exposure are also possible.

Data on typical use patterns
Data on typical use patterns of cosmetic products in which the notified chemical is proposed to be used are shown in the following tables for young children (2-4 year olds) and adults, respectively. The use of toothpaste is separately estimated for young children, as they represent a more susceptible receptor group. For the purposes of the exposure assessment, Australian use patterns for the product categories are assumed to be similar to those in Europe (SCCS, 2018). A child bodyweight of 12.5 kg (RIVM, 2006) and an adult bodyweight of 64 kg (enHealth, 2012) have been used for calculation purposes. In addition, 100% systemic exposure has been assumed. For adults it is assumed that the main exposure route is dermal absorption (i.e. mucous membranes), whereas in children it is assumed to be oral ingestion. Using these data, the total systemic exposure of the notified chemical is estimated to be 0.6880 mg/kg bw/day for children and 0.1842 mg/kg bw/day for adults.

Children's exposure (2-4 year old)

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Toothpaste	1,720[1]	0.5	1	**0.6880**

C = concentration (%); RF = retention factor; assumed brushing twice daily
Daily systemic exposure = (amount × C (%) × RF x oral absorption)/body weight (12.5 kg)

Adults' exposure

Product type	Amount (mg/day)	C (%)	RF	Daily systemic exposure (mg/kg bw/day)
Lipstick	57	0.5	1	0.0045
Toothpaste	2,750	0.5	0.05	0.0108
Mouthwash	21,620	0.5	0.10	0.1689
Total				**0.1842**

C = concentration (%); RF = retention factor; assumed brushing twice daily
Daily systemic exposure = (amount × C (%) × RF x oral absorption)/body weight (64 kg)

[1]RIVM (2006)

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	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – *in vitro* reconstructed human epidermis model (EpiDerm™)	non-irritating

Endpoint	*Result and Assessment Conclusion*
Eye irritation – *in vitro* bovine corneal opacity and permeability assay (BCOP)	non-irritating at 20% concentration
Skin sensitisation – mouse local lymph node assay	no evidence of sensitisation at 40% concentration
Repeat dose oral toxicity – rat, 90 days	NOAEL = 489.5/492.2 mg/kg bw/day (male/female)
Mutagenicity – bacterial reverse mutation	non-mutagenic
Genotoxicity – *in vitro* mammalian cell micronucleus test	non-genotoxic

Toxicokinetics
Given the low molecular weight (343.38 g/mol) and the partition coefficient (log Pow = 3.4 at 20 °C) of the notified chemical, it may be absorbed across biological membranes. However, dermal absorption may be limited by its low water solubility (1.25 × 10-4 g/L at 20 °C).

The notified chemical has a low water solubility and will be introduced as a solid powder containing particles in the respirable range (< 10 μm). Respirable particles that deposit in the lower respiratory tract cannot be cleared by mucous and ciliary mechanisms and may be retained deep in the lungs, with long-term inhalation possibly leading to lung overloading.

Acute Toxicity
The notified chemical is expected to have low acute oral toxicity based on a study conducted in rats.

No dermal or inhalation toxicity study data were submitted.

Irritation
The notified chemical was not considered to be a skin irritant based on the results of an *in vitro* human skin test using the EpiDerm reconstructed human epidermis model.

The notified chemical at 20% concentration was not considered to be an eye irritant based on the results of an *in vitro* bovine corneal opacity and permeability (BCOP) test.

Sensitisation
The notified chemical was found to be non-sensitising at 40% concentration in a mouse local lymph node assay.

Repeated Dose Toxicity
A repeated dose oral (diet) toxicity study on the notified chemical was conducted in rats, in which the test substance was administered at 29.4/29.4 mg/kg bw/day (male/female), 97.5/98.6 mg/kg bw/day (male/female) and 489.5/492.2 mg/kg bw/day (male/female) for 90 consecutive days.

The No Observed Adverse Effect Level (NOAEL) was established as 489.5 mg/kg bw/day for males and 492.2 mg/kg bw/day for females, based on no treatment-related adverse effects observed at all doses tested.

Mutagenicity/Genotoxicity
The notified chemical was found to be negative in a bacterial reverse mutation assay and in an *in vitro* mammalian cell micronucleus test in human lymphocytes.

Health Hazard Classification
Based on the available information, the notified chemical is not recommended for classification 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

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, the notified chemical is expected to be of low systemic toxicity. Eye irritation at high concentrations cannot be ruled out. Inhalation of dusts of the notified chemical may result in lung overloading effects, if inhaled at high levels and/or frequently.

Reformulation
Workers may experience dermal, ocular and inhalation exposure to the notified chemical (at ≤ 100% concentration) during reformulation. The use of local ventilation, enclosed/automated processes and PPE (i.e. protective clothing, goggles, impervious gloves and respiratory protection, if inhalation exposure may occur) are expected to minimise exposure.

Therefore, provided adequate control measures are in place to minimise worker exposure, including the use of automated processes and PPE, 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 use of oral care cosmetic products, for example dentists, may be exposed dermally to the notified chemical. Such professionals are expected to use PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, the exposure of such workers is expected to be very low and 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 oral and dermal (on lip) care cosmetic products containing the notified chemical at ≤ 0.5% concentration. The principal route of exposure will be oral and dermal while accidental ocular exposure is also possible.

Irritation
The notified chemical is not expected to be irritating to the skin and eyes at the proposed low use concentrations in lip and oral care cosmetic products.

Systemic Effects
The potential systemic exposure to young children (2-4 year olds) from the use of the notified chemical in toothpaste only was estimated to be 0.6880 mg/kg bw/day, while the potential systemic exposure to adults from the use of the notified chemical in lip and oral care cosmetic products was estimated to be 0.1842 mg/kg bw/day. Using a NOAEL of 489.5 mg/kg bw/day which was derived from a 90-day repeated dose oral diet toxicity study in rats on the notified chemical, the margin of exposure (MOE) was estimated to be 711 and 2,657 in children and adults, respectively. A MOE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences.

Therefore, based on the information available, the risk to the public associated with use of the notified chemical at ≤ 0.5% concentration in lip and oral care cosmetic products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will not be manufactured in Australia. The notified chemical may be imported into Australia neat and blended into lip and oral care cosmetic products or imported in finished oral care cosmetic products. Release of the notified chemical to the environment is unlikely except in the event of a transport accident or an accidental spill during handling. Accidental spills of formulated products containing the notified chemical are expected to be physically contained and then absorbed into inert material. The absorbed notified chemical is expected to be disposed of to landfill.

The reformulation process will involve both automated and manual transfer of the notified chemical into blending vessels, followed by blending operations that are expected to be highly automated and occur within a fully enclosed environment. The process will be followed by automated filling of the finished products into end-use containers of various sizes. Wastes containing the notified chemical generated during reformulation include equipment wash water, residues in empty import containers and spilt materials. Wastes may be collected and released to sewers, or disposed of to landfill in accordance with state and local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the annual import volume of the notified chemical is expected to be released to the aquatic compartment through sewers during its use in various oral care cosmetic products such as toothpaste and mouthwash. The notified chemical in dental floss and lipstick wiped to tissue paper is expected to be disposed of to refuse and expected to end up in landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that the majority of the annual import volume of the notified chemical will be released to the sewer through consumer use of lip and oral care cosmetic products. It is estimated by the notifier that 3% of the import volume of the notified chemical may remain in end-use containers. Wastes and residues of the notified chemical in empty containers are likely to either share the fate of the container 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. The notified chemical in dental floss and tissue paper used to remove lipstick is also expected to end up in landfill.

7.1.2. Environmental Fate

The results of a submitted biodegradability study of the notified chemical indicated that it is not readily biodegradable (1.6 % in 28 days; OECD TG 301 F). For the details of the environmental fate study please refer to Appendix C.

Following its use in oral care cosmetic products, the majority of the notified chemical is expected to enter the sewer system, before potential release to surface waters nationwide. Due to its chemical structure, moderate log Pow (3.4) and log K_{oc} (3.2), a significant amount of the notified chemical is expected remain in the effluent after release from STPs. The notified chemical released to surface waters is expected to partially adhere to sediment matter, but mainly be dispersed in the water. Consequently, the notified chemical is expected to be significantly bioavailable, however, the potential for bioaccumulation is low based on the log Pow. The notified chemical is not expected to be persistent in water but degradation in sediment, is expected to be slower. The sewage sludge containing the notified chemical residues may be sent to landfill or applied to soils for land remediation. The notified chemical is expected to ultimately degrade biotically and abiotically to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in most of the notified chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 100% release of the notified chemical into sewer systems nationwide over 365 days per annum. The extent to which the notified chemical is removed from the effluent in STP processes based on the properties of the notified chemical has not been considered for this scenario, and therefore no removal of the notified chemical during sewage treatment processes is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

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

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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.562 µg/L may potentially result in a soil concentration of approximately 3.75×10^{-3} mg/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 1.873×10^{-2} mg/kg and 3.75×10^{-2} mg/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 hr LC50 > 0.0943 mg/L (WSF)	Not harmful to fish up to the limit of water solubility
Daphnia Toxicity	48 hr EC50 > 0.079 mg/L (WSF)	Not harmful to aquatic invertebrates up to the limit of water solubility
Algal Toxicity	72 hr ErC50 > 0.119 mg/L (WSF)	Not harmful to algae up to the limit of water solubility

WSF = Water Soluble Fraction

Based on the above ecotoxicological data, the notified chemical is not expected to be acutely toxic up to the limit of its water solubility. Therefore, the notified chemical is not classified for acute or chronic toxicity under the Globally Harmonised System of Classification of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) for the aquatic compartment has not been calculated, since the notified chemical is not harmful to aquatic life up to the limit of its water solubility.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified chemical has not been calculated as a PNEC value is not available. The notified chemical is not readily biodegradable but has a low potential for bioaccumulation based on its log Pow. On the basis of the low aquatic hazard and the reported use pattern in lip and oral care cosmetic products, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 146.4 °C at 100.4 kPa

Method OECD TG 102 Melting Point/Melting Range
Remarks Differential scanning calorimetry method
Test Facility Exempt Information (6)

Boiling Point Decomposes without boiling at 330 °C

Method OECD TG 103 Boiling Point
Remarks Differential scanning calorimetry method
Test Facility Exempt Information (6)

Density 1,287 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids
Remarks Pycnometer method
Test Facility Exempt Information (7)

Vapour Pressure 3.8×10^{-14} kPa at 20 °C
1.3×10^{-13} kPa at 25 °C
2.7×10^{-11} kPa at 50 °C

Method OECD TG 104 Vapour Pressure
Remarks Effusion method: vapour pressure balance used to create a vapour pressure curve. The vapour pressure of the notified chemical at 20 °C, 25 °C, and 50 °C was extrapolated from this curve.
Test Facility Exempt Information (8)

Water Solubility 1.25×10^{-4} g/L at 20 °C

Method OECD TG 105 Water Solubility
Remarks Column Elution Method
Test Facility Exempt Information (13)

Partition Coefficient (n-octanol/water) log Pow = 3.4 at 20 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method
Test Facility Exempt Information (11)

Particle Size D_{10}: 5.1 µm
D_{50}: 27.5 µm
D_{90}: 142 µm

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions
ISO 13320:2009 Particle Size Analysis – Laser Diffraction Methods
EPA OCSPP Test Guideline 830.7520

	Test 1	*Test 2*	*Average*
D_{10}	5.3 µm	4.9 µm	5.1 µm
D_{50}	28.3 µm	26.7 µm	27.5 µm
D_{90}	143.4 µm	140.5 µm	142.0 µm

Remarks Laser diffraction. Smallest particle size was in the range 0.145 µm – 0.178 µm, and the largest particle size was in the range 1,153.480 µm and 1,408.654 µm. Approximately 90%

	of particles are expected to be less than 100 µm and less than 25 % of particles are expected to be less than 10 µm.
Test Facility	Exempt Information (9)

Flammability Not flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks	The test substance melted but could not be ignited by a flame applied for at least 2 minutes.
Test Facility	Exempt Information (10)

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
Species/Strain	Rat/Wistar/Crl:WI (Han)
Vehicle	0.5% sodium carboxymethylcellulose in doubly distilled water
Remarks – Method	No significant protocol deviations

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	No clinical signs were observed.
Effects in Organs	No abnormalities were noted at macroscopic examination.
Remarks – Results	All animals showed expected body weight gains over the observation period.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	Exempt Information (4)

B.2. Skin Corrosion/Irritation – *In Vitro* Reconstructed Human Epidermis Model

TEST SUBSTANCE	Notified chemical
METHOD	For skin corrosion: OECD TG 431 *In vitro* Skin Corrosion: Reconstructed Human Epidermis Test Method For skin irritation: Similar to OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human Epidermis Test Method
Vehicle	None
Remarks – Method	No significant protocol deviations. For the corrosion test, two EpiDerm™ tissue samples were incubated with the test substance for 3 minutes and 60 minutes, respectively. For the irritation test, three EpiDerm™ tissue samples were incubated with the test substance for 60 minutes followed by a 42-hour post-incubation period. In a preliminary test the test substance was shown not to directly reduce MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolim bromide]. Therefore, the study was performed on viable tissues. Corrosion test: Negative control: highly de-ionized water Positive control: 8 N potassium hydroxide solution Irritation test: Negative control: phosphate buffered saline Positive control: 5% (w/v) sodium dodecyl sulphate

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*		*Relative Mean Viability (%)*		*SD of Relative Mean Viability*	
	3 min	*60 min*	*3 min*	*60 min*	*3 min*	*60 min*
Corrosion test						
Negative control	1.3642	1.7265	100.0	100.0	10.1823	5.5154
Test substance	1.6812	1.7895	123.2	103.7	6.6468	1.0607
Positive control	0.3387	0.2115	24.8	12.3	0.7071	1.3435
Irritation test						
Negative control	1.8679		100.0		3.91	
Test substance	1.9672		105.3		9.68	
Positive control	0.1225		6.6		0.65	

OD = optical density; SD = standard deviation

Remarks – Results

Based on the mean relative tissue viability of ≥ 50% after 3 min exposure and ≥ 15% after 60 min exposure, the test substance is not predicted to be corrosive according to UN GHS.

Based on the mean relative tissue viability was > 50% after 60 min exposure (followed by a 42-hour post-incubation period), the test substance is expected to to be a non-irritant.

The positive and negative controls performed as expected.

CONCLUSION

The notified chemical is not classifiable as a skin irritant according to the GHS criteria.

TEST FACILITY

Exempt Information (2)

B.3. Eye Irritation – *In Vitro* Bovine Corneal Opacity and Permeability Assay (BCOP)

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

Vehicle

Saline (0.9% w/v NaCl in deionised water)

Remarks – Method

No significant protocol deviations. The test substance was tested as a 20% (w/v) suspension in saline.

Positive control: 10% (w/v) benzalkonium chloride in 0.9% saline
Negative control: saline (0.9% NaCl in deionised water)

RESULTS

Test Material	*Mean Opacities of Triplicate Tissues (SD)*	*Mean Permeabilities of Triplicate Tissues (SD)*	*IVIS (SD)*
Vehicle control	0.33	0.087	1.65 (± 0.57)
*Test substance**	2.00	0.041	2.61 (± 2.64)
*Positive control**	121.34	0.055	122.16 (± 11.18)

SD = Standard deviation; IVIS = in vitro irritancy score
* Corrected for background values

Remarks – Results

The in vitro irritancy score (IVIS) for the test substance was lower than the cut-off value for UN GHS no category (≤ 3), indicating it is not requiring eye irritation classification.

The positive and negative controls performed as expected.

CONCLUSION	The test substance (notified chemical at 20% concentration) is not classifiable as an eye irritant according to the GHS criteria.
TEST FACILITY	Exempt Information (12)

B.4. Skin Sensitisation – LLNA

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA/J
Vehicle	1% Pluronic® L 92 Surfactant in highly de-ionised water
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 significant protocol deviations

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node pair)*	*Stimulation Index (test/control ratio)*
Test Substance			
0% (vehicle control)	5 F	1292.2	1.00
40%	5 F	934.0	0.72

Remarks – Results	No signs of systemic toxicity were observed. All animals showed the expected body weight gains. The test substance did not induce a biologically relevant response in the auricular lymph node cell counts. The test substance did not elicit a stimulation index (SI) ≥ 3 and is therefore not considered as a skin sensitiser.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical at 40% concentration under the conditions of the test.
TEST FACILITY	Exempt Information (3)

B.5. Repeat Dose Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents
Species/Strain	Rat/Crl: Sprague-Dawley CD IGS rats
Route of Administration	Oral – diet
Exposure Information	Total exposure days: 90 days Dose regimen: 7 days per week
Vehicle	2016CM Harlan Teklad Global Rodent Diet
Remarks – Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration mg/kg bw/day)*		*Mortality*
		Nominal	*Actual*	
Control	10 M, 10 F	0	0	0/20
Low Dose	10 M, 10 F	30	M: 29.4, F: 29.4	0/20
Mid Dose	10 M, 10 F	100	M: 97.5, F: 98.6	0/20
High Dose	10 M, 10 F	500	M: 489.5, F: 492.2	0/20

Mortality and Time to Death
There were no unscheduled deaths.

Clinical Observations
No significant clinical observations were recorded. Clinical observations included unilateral red/black ocular discharge (1/10 males and 1/10 females, low-dose group), alopecia (5/10, 4/10 and 1/10 males in the control, low-, and high-dose group respectively, and 1/10 females in the low-, mid- and high-dose groups), scab on neck (1/10 males, low-dose group), broken upper incisor (1/10 males, low-dose group), and malocclusion of the upper incisor (1/10 males and 1/10 females of the low-dose group). The study authors did not consider these effects to be related to the test substance as no dose-dependent relationship was observed, the effects were transient in nature, were also observed in the control group or were toxicologically insignificant.

All animals showed the expected body weight gains. A statistically significant decrease in body weight gain in week 1 was observed in females in the high-dose group when compared to control animals. This observation was transient and not observed over the remainder of the study.

Laboratory Findings – Clinical Chemistry, Haematology,Coagulation and Urinalysis
When compared to controls statistically significantly lower levels of alanine aminotransferase were observed in females in the high-dose group and statistically significantly higher levels of potassium were observed in females in the low-dose group. Statistically significantly lower absolute basophil levels (high-dose males), haemoglobin and haematocrit levels (mid-dose females) and mean corpuscular haemoglobin concentration (low-dose females) were recorded compared to values in control animals. No statistically significant difference in coagulation parameters were observed between the test groups and the control. No statistically significant differences were observed in the urinalysis parameter of animals exposed to the test substance and those in the control group.

The differences observed were within the range of historical values, only observed in one sex, did not exhibit a dose-dependent relationship or showed no direct histologic correlation, and as such the study authors did not consider them to be test substance-related.

Effects in Organs
No adverse ophthalmological observations were recorded in animals exposed to the test substance. Fluid-filled uteri were observed (2/10 low-dose, 4/10 mid-dose, and 4/10 high-dose females). These changes corresponded to microscopic luminal dilation of the uterus. This was attributed to variations in the estrous cycle and were not considered to be test substance-related by the study authors. A serosal surface cyst-like raised area was observed (1/10 low-dose female), but was not considered to be test substance-realted by the study authors. Adhesion of the right upper lobe of the liver to the diaphragm (1/10 mid-dose male) was determined by the study authors to be a spontansous alteration due to focal fibrosis.

Renal tubliar cell hyperplasia was observed with chronic progressive nephropathy (1/10 high-dose male) but was considered an isolated occurance by the study authors. The study authors observed slight to moderate laryngeal inflammation with evidence of epiglottal cartilage necrosis (1/10 control-, 1/10 high-dose male, and 2/10 high-dose females) consistent with morphological similarities in historical observations. Inflammatory cell infiltrates were observed in the prostate gland interstitium (4/10 contol-, and 4/10 high dose males) and glandular lumens (3/10 high-dose males). No microscopic findings were attributed to the test substance.

The following absolute and relative organ weights were observed:
Statistically significantly lower brain weight in low-dose males and high-dose females, and thymus weight in mid- and high-dose females (no dose-dependent relationship). Statistically significantly higher liver : body weight ratio high-dose males and mid- and high-dose females (no dose-dependent relationship). Statistically significantly lower thymus : body weight ratio in mid-dose females. Statistically significantly higher kidney : brain weight ratio in low-dose females and liver : brain weight ratio in low-, mid- and high-dose females (highest ratio in low-dose females with dose dependent decrease in mid- and high-dose females).

Remarks – Results
Exposure to ≤ 489.5 mg/kg bw/day male and ≤ 492.2 mg/kg bw/day female of the notified chemical resulted in no toxicologically significant observations attributed to the notified chemical by the study authors over the 90 day period. No unscheduled mortalities were obsevered.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 489.5 mg/kg bw/day for males and 492.2 mg/kg bw/day for females in this study.

TEST FACILITY Exempt Information (16)

B.6. Genotoxicity – Bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2)
Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA
Metabolic Activation System S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Tests 1 and 2 a) With metabolic activation: 0, 22, 110, 550, 2,750, 5,500 µg/plate
b) Without metabolic activation: 0, 22, 110, 550, 2,750, 5,500 µg/plate
Vehicle Dimethylsulfoxide
Remarks – Method No significant protocol deviations. No preliminary assay was performed.

Positive controls: without metabolic activation – N-methyl-N'-nitro-N-nitrosoguanidine (TA1535, TA100), 4-nitro-o-phenylenediamine (TA98), 9-aminoacridine (TA1537), 4-nitroquinoline-N-oxide (WP2 uvrA); with metabolic activation – 2-aminoanthracene

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*			
Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5,500	≥ 110	negative
Test 2	-	> 5,500	≥ 110	negative
Present				
Test 1	-	> 5,500	≥ 110	negative
Test 2	-	≥ 5,500	≥ 110	negative

Remarks – Results No significant, dose related increases in the frequency of revertants were observed for any of the bacterial strains, with any dose of the test substance, with or without metabolic activation.

Positive and negative controls performed as expected.

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

TEST FACILITY Exempt Information (1)

B.7. Genotoxicity – *In Vitro* Mammalian Cell Micronucleus test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 487 *In vitro* Mammalian Cell Micronucleus Test
Species/Strain Human
Cell Type/Cell Line Lymphocytes
Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver
Vehicle Dimethyl sulphoxide
Remarks – Method No significant protocol deviations. A preliminary assay established the dose range chosen for the main experiment.

Positive controls: without metabolic activation – Mitomycin C and Vinblastine; with metabolic activation – Cyclophosphamide.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hour)*	*Harvest Time (hour)*
Absent			
Test 1	0, 5, 10*, 20, 25, 30*, 35, 40, 45, 50, 60*, 80, 100	3	72
Test 2	0, 2, 4, 8*, 9, 10, 11, 12, 13, 14*, 16, 20*, 40	24	72
Present			
Test 1	0, 10*, 20, 30*, 40, 45, 50, 55*, 60*, 65, 70, 80, 100	3	72

*Cultures selected for metaphase analysis

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 38.88	≥ 60.00	≥ 30.00	negative
Test 2	≥ 14.00	≥ 20.00	≥ 38.88	negative
Present				
Test 1	≥ 64.80	≥ 55.00	≥ 30.00	negative

Remarks – Results

No significant increase in the number of micronucleated binucleate cells was observed in human lymphocytes exposed to the test substance at any of the concentrations tested with or without metabolic activation.

Positive and negative controls performed as expected.

CONCLUSION

The notified chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Exempt Information (5)

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
Inoculum	Activated Sewage Sludge
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	None
Remarks – Method	The study was carried out in accordance with the test guidelines and GLP where no deviations were recorded. The test was run in parallel to controls and the reference substance, sodium benzoate.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation*
1	0.6	1	24.9
7	1.4	7	75.7
28	1.6	28	92.9

*Mean of two replicates

Remarks – Results	The study met all validity criteria. The standard reference material reached more than ≥ 60% degradation within 4 days. The difference between replicate values of CO_2 production was < 20%; the oxygen uptake of the blank control vessels was 22.0 mg/L which did not exceed 60 mg/L and the toxicity control reached ≥ 25% degradation within 6 days. The biodegradation of the reference substance was not inhibited by the test substance in the toxicity control. The test substance attained 1.6% degradation after 28 days and therefore cannot be considered to be readily biodegradable.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	Exempt Information (17)

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
Species	*Gobiocypris rarus* (Rare minnow)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	UPLC-UV
Remarks – Method	The study was carried out in accordance with the test guidelines and GLP. Following a preliminary range-finding test, a definitive limit test was conducted at a nominal concentration of 10 mg/L (stirred for 24 hours and filtered by a 0.45 µm membrane filter) under semi-static conditions with renewal every 48 hours. A positive control was run with potassium dichromate, prior to the definitive study.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	7	0	0	0	0	0
10	0.0943*	7	0	0	0	0	0

*Geometric mean of the mean concentrations in fresh and old media
WSF = Water Soluble Fraction

LC50	> 0.0943 mg/L at 96 hours (WSF)
NOEC	0.0943 mg/L at 96 hours
Remarks – Results	All of the validity criteria for the test were satisfied. The dissolved oxygen concentration was in the range of 64.2 - 95.9% and held between pH 7.90 - 8.08 at approximately 23.1 - 24.6 °C during the test. The result from the positive control (24 h LC50 = 464.31 mg/L) was within the range of the lab ring test.
CONCLUSION	The notified chemical is not harmful to fish up to its water solubility limit.
TEST FACILITY	Exempt Information (18)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV
Remarks – Method	The test medium was prepared by mixing the test substance into test water at a loading rate of 100 mg/L and stirred for 24 hours. After stirring, the suspension was filtered through a 0.45 µm membrane filter. The undiluted filtrate was used as test medium. A positive control was run less than six months prior to the definitive study.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
100	0.079*	20	0	0

*Mean measured concentration
WSF = Water Soluble Fraction

EC50	> 0.079 mg/L at 48 hours (WSF)
NOEC	0.079 mg/L at 48 hours
Remarks – Results	The test is valid. No daphnids showed immobilisation or other signs of disease or stress in the controls and the dissolved oxygen concentration at the end of the test was ≥ 3 mg/L in the control and test vessels. The measured concentration of the test substance was 93 and 72 µg/L at the start of the renewal periods. At the end of the two 24-hour renewal periods, 89 and 94% of the initially measured concentration were found. The result of the positive control, potassium dichromate, 24-hour EC50 = 0.78 mg/L was within the range given by the guideline (24-hour EC50 = 0.60-2.1 mg/L).

CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to its water solubility limit.
TEST FACILITY	Exempt Information (14)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Pseudokirchneriella subcapitata* (Green Algae)
Exposure Period	72 hours
Concentration Range	Nominal: 4.5, 10, 22, 45, 100 mg/L Actual: 0.004, 0.011, 0.024, 0.051 and 0.119 mg/L (Geometric Means)
Auxiliary Solvent	None
Water Hardness	15 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UV
Remarks – Method	The study was carried out in accordance with the test guideline and GLP. After preliminary range-finding tests, the media were prepared by mixing the test substance into test water at a loading rate of 100 mg/L, stirred for 24 hours and filtered through a 0.45 µm membrane filter. The undiluted filtrate was used as the highest test medium and diluted for the preparation of the lower test concentrations. A positive control was run less than six months prior to the definitive study.

RESULTS

Biomass		*Growth*	
EyC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
> 0.119 (WSF)	0.011	> 0.119 (WSF)	0.011

WSF = Water Soluble Fraction

Remarks – Results	The validity criteria were fulfilled. In the control, the biomass increased by a factor of 261 over 72 hours (≥ 16). The mean coefficient of variation of the daily growth rates in the control (section-by-section growth rates) was 9.7% (≤ 35%). The coefficient of variation of the average specific growth rates in the replicates of the control after 72 hours was 0.6% (≤ 7%). The 72-hour EC50 of the positive control potassium dichromate was 0.74 mg/L which was within the range recommended by the guideline (0.60-1.03 mg/L).
CONCLUSION	The test substance is not harmful to algae up to its limit of water solubility.
TEST FACILITY	Exempt Information (15)

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