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June 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fatty acids, tall-oil, compds. with oleylamine

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 on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1685	ResChem Technologies Pty Ltd	Fatty acids, tall-oil, compds. with oleylamine	Yes	≤ 10 tonnes per annum	Component of industrial coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical/polymer is presented in the following table.

Hazard Classification	*Hazard Statement*
Sensitisation, Skin (Category 1A)	H317 – May cause an allergic skin reaction
Serious Eye Damage/Eye Irritation (Category 1)	H318 – Causes serious eye damage

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard Classification	*Hazard Statement*
Acute aquatic hazard (Category 2)	H402 - Toxic to aquatic life

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin Sensitisation (Category 1A): H317 – May cause an allergic skin reaction
  - Serious eye damage/eye irritation (Category 1): H318 – Causes serious eye damage

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

Health Surveillance

- As the notified chemical is a strong skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation and/or eye irritation.

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 if possible
  - Adequate general 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 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 and use:
  - Impervious gloves
  - Protective clothing
  - Safety 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.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- 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 containment 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 notified chemical is intended to be used in products available to the public, including do-it-yourself (DIY) users.

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of industrial coatings, 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.

No additional secondary notification conditions are stipulated.

Safety Data Sheet
The SDS of the product containing 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)
ResChem Technologies Pty Ltd (ABN: 90 315 656 219)
Unit 9, 1-3 Jubilee Avenue
WARRIEWOOD NSW 2102

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for dissociation constant, particle size, flammability, dermal and inhalation toxicity, repeated dose toxicity and *in vivo* genotoxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (REACH) (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ANTI-TERRA-203 (product containing the notified chemical)

CAS NUMBER
85711-55-3

CHEMICAL NAME
Fatty acids, tall-oil, compds. with oleylamine

MOLECULAR WEIGHT
< 600 g/mol

ANALYTICAL DATA
Reference NMR, IR, LC and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
100 % (UVCB)

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Expected to be stable under normal conditions of use.

DEGRADATION PRODUCTS
No degradation is expected under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light brown liquid (product containing the notified chemical at ≤ 25%)

Property	*Value*	*Data Source/Justification*
Freezing Point	9 °C	Measured

Property	*Value*	*Data Source/Justification*
Boiling Point	Not determined	Decomposes at temperature above 140 °C without boiling
Density	910 kg/m^3 at 20 °C	Measured
Vapour Pressure	5 x 10^{-6} kPa at 25 °C	Measured
Water Solubility	<1 mg/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Not determined due to low water solubility
Partition Coefficient (n-octanol/water)	log Pow > 6.2 at pH 4 < 2.6 at pH 7 < 1.0 at pH 9	Measured
Adsorption/Desorption	log K_{oc} > 3.9 at pH 4 < 1.3 at pH 9	Measured
Dissociation Constant	Not determined	The notified chemical is expected to be fully dissociated under environmental conditions
Flash Point	No flash point below 180ºC	Measured
Autoignition Temperature	342 °C	Measured
Explosive Properties	Not determined	Based on the structure, the notified chemical is not expected to be explosive.
Oxidising Properties	Not determined	Based on the structure, the notified chemical is not expected to be oxidising.
Viscosity	10000 to 90000 mPa.s at 20ºC (shear dependent) 200 mPa.s at 40ºC (independent of shear rate)	Measured

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 in the product ANTI-TERRA-203 at ≤ 25% concentration, for reformulation into finished products (industrial coatings).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Melbourne or Sydney

TRANSPORTATION AND PACKAGING
The product containing the notified chemical at ≤ 25% concentration will be imported in 25 kg and 200 kg steel drums. It will be stored at the notifier's facility before being transported to reformulation sites. The end use product will be packed in 25 kg or 200 kg container sizes.

USE
The notified chemical will be used as an additive in a range of industrial and protective coatings. The final concentration of the notified chemical in the end-use coatings will be ≤ 0.7%.

OPERATION DESCRIPTION

Reformulation
At the coating manufacturing sites, the product containing the notified chemical at ≤ 25% concentration will be manually weighed or metered directly from the storage drums into a stainless steel blending tank and mixed with pigments and resin to form the mill base. The mill base will then be pumped into a large mixing vessel to which the remaining additives and resin will be added to form the finished coating product. The finished coating product (containing notified chemical at ≤ 0.7%) will be fed into containers by gravity from the bottom of the mixing vessel through a filter and filling lines. All processes will occur under exhaust ventilation in an industrial setting.

End Use
Industrial/protective coatings containing the notified chemical at ≤ 0.7% concentration will be applied by industrial and professional users. Industrial application is primarily by spray (40%) and roller (50%), with limited application by brush (10%). It is expected that spray applications will be conducted primarily in spray booths at industrial sites. The overspray will be collected within the spray booth on protective materials (e.g., kraft paper or newspaper). Treatment of articles by dipping and pouring may also be performed.

Maintenance and cleaning of equipment used in blending the coating and/or coating applicators will occur on a regular basis. The application equipment is expected to be washed using industrial solvent (such as mineral spirit, aromatic solvents, and polar solvents) and disposed of via licensed waste management contractors.

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)*
Waterside workers	4	50
Transport and storage	4	100
Manufacture- (Blending-coating production)	5	200
Quality control	2	100
Applications	6	260

EXPOSURE DETAILS
Transport and storage
Transport and storage workers are not expected to be exposed to the notified chemical except in an unlikely event of an accident where the packaging is breached.

Reformulation
During reformulation process, workers may be exposed via dermal and ocular routes to the notified chemical (at ≤ 25% concentration) such as during mixing of the notified chemical to make final coating products. As the notified chemical is not expected to be volatile, inhalation exposure is unlikely to occur unless aerosols are generated. The notifier stated that worker exposure is expected to be limited by the use of ventilated areas, and by the use of PPE including gloves, safety glasses, appropriate industrial clothing and respiratory equipment (when deemed necessary).

Coating Applications
At end-use sites, dermal, ocular and/or inhalation exposure to the notified chemical (at ≤ 0.7% concentration) may occur during mixing and manual transfer of the coating to spraying equipment, during application and also during equipment cleaning and maintenance. Possible inhalation exposure to the notified chemical from spraying may occur. However, exposure will be mitigated by the use of ventilated spray booths at industrial facilities. The notifier stated that air respirators will also be worn by workers when necessary, and exposure will be further reduced by the use of PPE (safety goggles, gloves, protective clothing).

Dermal and ocular exposure to the notified chemical (at ≤ 0.7%) may also occur during brush and roller applications, spraying (without spray booths) and treatment of articles by dipping and pouring, particularly during

manual decanting and manual application. Dermal and ocular exposure is expected to be minimised by the stated use of PPE such as protective clothing, safety glasses and gloves. Once the coatings are dried they will be bound into the coating matrix and the notified chemical not expected to be available for exposure.

Maintenance and cleaning of equipment
Dermal, ocular and inhalation exposure to the notified chemical at ≤ 0.7% concentration may occur during regular maintenance and cleaning of equipment used to apply the coating. The notifier stated that workers will wear gloves, safety glasses and protective clothing in order to minimise any possible exposure.

6.1.2. Public Exposure

The products containing the notified chemical will only be used by industrial and professional users. They will not be sold to the public and DIY users.

Members of the public may come into contact with articles coated with the finished industrial coating products containing the notified chemical. However, once dried the notified chemical is expected to be bound into the inert matrix of the coating and will not be available for further exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical and a structurally similar analogue 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 > 2000 mg/kg bw; low toxicity
Skin irritation – *in vitro*- EPISKIN Skin Irritation Test	non-irritating
Eye irritation – rabbit	severely irritating
Skin sensitisation – mouse local lymph node assay	sensitiser (EC3=1.9%)
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test*– rat	NOAEL(systemic) = 7.1 mg/kg bw/day NOAEL (reproductive/developmental) = 75 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test in human lymphocytes	non genotoxic

*analogue data

Toxicokinetics, Metabolism and Distribution
Although the relatively low molecular weight (< 600 g/mol) and partition coefficient (log Pow < 2.6 at pH = 7) of the notified chemical favour percutaneous absorption, the absorption may be limited by the low water solubility (<1 mg/L at 20 °C) of the notified chemical.

Acute Toxicity
The notified chemical was found to have low acute oral toxicity based on a study conducted in rats. No acute dermal and inhalation toxicity data were provided for the notified chemical.

Irritation and Sensitisation
The notified chemical was shown to cause serious damage to the eyes in an *in vivo* rabbit study. An area of pannus formation was apparent in one of three animals tested, 9 days after treatment with the notified chemical. The study authors stated that this animal was humanely sacrificed due to the irreversible nature of this corneal finding. Based on these results, the notified chemical is classified as a Category 1 eye irritant according to section 3.3.2.8 of GHS classification, where a chemical is a Category 1 eye irritant if it produces severe effects on the eyes in at least one animal, that are not expected to reverse or have not fully reversed within an observation period (normally 21 days).

Based on the results of an *in vitro* skin irritation study (using reconstructed human epidermis test), the notified chemical was not considered as irritating to the skin.
The notified chemical was found to be a skin sensitiser in a local lymph node assay (LLNA) in mice, with reported stimulation indices of 1.2, 4.2 and 10.4 at 1%, 2.5% and 5% concentration, respectively. The calculated EC3 value was 1.9%, warranting classification of the notified chemical as a Category 1A skin sensitiser.

Repeated Dose Toxicity
No data are provided for the notified chemical. In a combined repeat dose and reproductive/developmental toxicity screening test, the analogue chemical was administered to rats by oral gavage at doses of 7.1, 21.9 and 75 mg/kg bw/day for 5 weeks in male animals (10/dose) and from 14 days before mating to day 6 of lactation in female animals (10/dose). Additional non-mated females (5/dose) were also treated for 5 weeks. No treatment-related mortality was noted during the study.

A no-observed-adverse-effect-level (NOAEL) for systemic toxicity was considered to be 7.1 mg/kg bw/day for both sexes based on the foamy macrophages observed in the gut mucosa of rats at 21.9 and 75 mg/kg bw/day, for which a cause was not identified. Other related effects at 75 mg/kg bw/day included a thickened jejeunum and enlarged mesenteric lymph nodes. In an earlier 7-day preliminary study, higher levels of dosing at (300 or 1,000 mg/kg) led to bodyweight loss and multiple macroscopic changes in the gastrointestinal tract (details not available).

Mutagenicity/Genotoxicity
In a reverse gene mutation assay conducted using *Salmonella typhimurium* strains TA100, TA1535, TA98, TA1537 and *Escherichia coli* strain WP2 uvrA (pKM101), the notified chemical was not mutagenic at concentrations up to 5 mg/plate with or without an exogenous metabolic activation system.

The notified chemical was negative in an *in vitro* mammalian cell chromosome aberration test conducted using human lymphocytes.

Reproductive toxicity
No data were provided for the notified chemical. There was no evidence of adverse reproductive or developmental effects in rats in a combined repeat dose reproductive/developmental screening study conducted on the analogue chemical. The highest dose tested (75 mg/kg bw/day) was reported in this study as the no-observed-effect-level (NOEL) for reproductive/developmental toxicity. However, a lower number of implantation sites, litter size and live birth index were reported at this dose level compared to the control group (not statistically significant), indicating the highest dose tested was the NOAEL.

Health Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	***Hazard Statement***
Sensitisation, Skin (Category 1A)	H317 – May cause an allergic skin reaction
Serious Eye Damage/Eye Irritation (Category 1)	H318 – Causes serious eye damage

6.3. Human Health Risk Characterisation
Based on the available information, the notified chemical is a strong skin sensitiser and it could cause severe eye irritation. It is expected that eye irritation effects would be significantly reduced at the concentration in end use products (≤ 0.7%), but skin sensitisation cannot be ruled out at this concentration.

6.3.1. Occupational Health and Safety
During reformulation and application of coatings containing the notified chemical, dermal, ocular and inhalation exposure of workers and consequent risk is expected to be limited by the use of engineering controls and PPE. Once the coating has dried and cured, the notified chemical will be bound within an inert solid matrix and is not expected to be available for exposure.

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not expected to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
The notified chemical will be used in industrial settings only and will not be made available to the public. Members of the public may come into contact with coated articles containing the notified chemical; however, once the coating has dried and cured, the notified chemical is expected to be bound into an inert matrix and will not be available for exposure.

Based on the assessed use pattern, the risk to the public from use of the notified chemical 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 is not manufactured in Australia and is imported in a sealed container. Any potential release would occur from accidental spills. In the case of accidental spills, the notified chemical is to be cleaned up using an inert, absorbent material and disposed of by a licensed waste contractor. During product reformulation, the notifier estimates that up to 1% of the notified chemical may be lost as a result of spillages during reformulation.

RELEASE OF CHEMICAL FROM USE

The notified chemical is to be used as a surface coating applied by brush, roller or spray gun method. It is estimated that up to 30% of the notified chemical will be lost to overspray during the application process, which will be conducted in spray booths where the notified chemical will be collected on booth lining paper and filters and subsequently disposed of to landfill. The notifier estimates that up to 1% of the notified chemical will be released into the sewer system from equipment washings and a further 1% may be released by accidental spills.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical is expected to share the fate of the substrate it is applied to, which is expected to be eventually disposed of to landfill at the end of its useful life. Some of the notified chemical may be used on metal substrates which have the potential to enter the metal recycling process. Residues of the notified chemical may remain in the containers. Empty containers are to be disposed of to landfill.

7.1.2. Environmental Fate

The majority of the notified chemical is expected to share the fate of the articles which it is applied to, which will eventually be disposed of to landfill as a part of the cured coating matrix. The notified chemical is not expected to be mobile, bioavailable or readily biodegradable in this form. The notified chemical is not expected to be bioaccumulative in the cured matrix. In landfill, the notified chemical is expected to ultimately degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen. During the metal recycling process the notified chemical is expected to be thermally decomposed to form water and oxides of carbon and nitrogen. The notifier estimates that up to 2% of the notified chemical may be released into the sewer from wastes generated during use. In the environment, the notified chemical is readily biodegradable (87% degradation after 28 days) and is not expected to be bioaccumulative. For the details of the environmental fate studies refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in a portion of the notified chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 2% release of the notified chemical into sewer systems nationwide over 260 working 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	10,000	kg/year
Proportion expected to be released to sewer	2%	
Annual quantity of chemical released to sewer	200	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.77	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	

PEC - River:	0.16	µg/L
PEC - Ocean:	0.02	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	EC50 > 8.27 mg/L WAF	Not harmful to fish at the limit of water solubility
Daphnia Toxicity	EL50 = 15.2 mg/L	Harmful to invertebrates
Algal Toxicity	ErL50 = 7.43 mg/L NOEC = 3.05	Toxic to algal growth

Based on the above ecotoxicological endpoints, the notified chemical is expected to be toxic to algae, and harmful to invertebrates. Therefore, the notified chemical is classified as 'Acute Category 2: toxic to aquatic life' according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009). The notified chemical is readily biodegradable and is not bioaccumulative. Therefore, the notified chemical is not formally classified under the GHS for long-term hazard.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration was calculated using the most sensitive endpoint (Algae ErL50 = 7.43) with an assessment factor of 100 as acute endpoints for three trophic levels were provided.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ErL50 (Algal)	7.43	mg/L
Assessment Factor	100.00	
Mitigation Factor	1.00	
PNEC:	74.30	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.16	74.3	<0.01
Q - Ocean:	0.02	74.3	<0.01

The risk quotient (Q=PEC/PNEC) has been calculated based on the worst-case scenario. The conservative risk quotient has been calculated to be significantly less than 1 in both river and ocean compartments.

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 9 °C

Method	OECD TG 102 Melting Point / Melting Range ASTM Test Method D97 Pour Point Measurement for Freezing Point
Remarks	Cloud and pour point apparatus were used.
Test Facility	HLS (2011a)

Boiling Point Not determined

Method	OECD TG 103 Boiling Point
Remarks	Used the Siwoloboff method. The test item decomposed without boiling at temperatures above approximately 140 °C.
Test Facility	HLS (2011a)

Density 910 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	A comparison pycnometer was used.
Test Facility	HLS (2011a)

Vapour Pressure 5 x 10^{-6} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	A vapour pressure balance was used.
Test Facility	HLS (2011a)

Water Solubility < 1 mg/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Flask Method. Concentration was analysed by Total Organic Carbon (TOC) in solution.
Test Facility	HLS (2011a)

Partition Coefficient (n-octanol/water) log Pow > 6.2 at pH 4 and 25 °C
< 2.6 at pH 7 and 25 °C
< 1.0 at pH 9 and 25 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method
Test Facility	HLS (2011a)

Adsorption/Desorption log K_{oc} > 3.9 at pH 4
< 1.3 at pH 9

Method	OECD TG 106 Adsorption – Desorption Using a Batch Equilibrium Method
Remarks	Analysis was not conducted at pH 7.
Test Facility	HLS (2011a)

Flash Point No flash point below 180 °C

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Pensky-Martens closed cup flash point apparatus was used. No flash was observed before the test substance appeared to boil at approximately 180 °C.
Test Facility	HLS (2011a)

Autoignition Temperature 342 °C

Method	EC Method A.15 British Standards Institute. Method of Test for Ignition Temperature of Gases & Vapours, BS 4056
Remarks	A furnace consisting of a refractory cylinder fitted with thermocouples was used.
Test Facility	HLS (2011a)

Viscosity 10000 to 90000 mPa.s at 20ºC (shear dependent)
200 mPa.s at 40ºC (independent of shear rate)

Method	OECD TG 114 Viscosity of Liquids
Remarks	A rotational viscometer was used.
Test Facility	HLS (2011a)

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	Female CD (Crl:CD 'SD') Rat
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 females	2,000	None
1	3 females	2,000	None

LD50	>2,000 mg/kg bw
Signs of Toxicity	No clinical signs were observed.
Effects in Organs	No gross abnormalities were detected at necropsy.
Remarks – Results	All animals have achieved satisfactory gains in bodyweight over the study period.

CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	HLS (2011c)

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

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method EpiSkin™ Reconstituted Human Epidermis Model (2010)
Vehicle	None
Remarks – Method	No significant protocol deviations. Standard MTT assay was used to determine cell viability. The test substance (10 µL) was applied to the tissues in triplicate. The tissues were incubated for 42 hours at 37 °C following an exposure period of 15 minutes. Positive and negative controls were run in parallel with the test substance: Negative control (NC): Phosphate buffered saline with Ca^{2+} and Mg^{2+} Positive control (PC): sodium dodecyl sulphate (5% in distilled water) The test chemical interacted with the MTT and therefore it was necessary to run colour correction tissues. The results below are for the second test. The initial test was not reported, as the standard deviation of the negative control results did not meet the criterion of < 18, and only 2/3 of the replicate tissues gave values indicating that the chemical was non-irritating.

RESULTS

Test Material	*Relative Mean Viability* (%)*	*SD of Relative Mean Viability*
Negative control	100	± 2.5
Test substance	92.8	± 2.4
Positive control	26.7	± 13.6

*Tissue viability as percentage of mean optical density of negative control; SD = standard deviation

Remarks – Results

As the mean tissue viability was > 50%, the test substance is considered a non-irritant under the conditions of the test.

The criteria for acceptance of both the negative and positive controls were satisfied, as were the requirements for standard deviation between the test substance replicates.

CONCLUSION

Based on the mean tissue viability of > 50%, the notified chemical is not considered as irritating to the skin to classify it as a skin irritant according to the GHS criteria.

TEST FACILITY

HLS (2011d)

B.3. Eye Irritation – Rabbit

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion (2005)

Species/Strain: Rabbit/New Zealand White

Number of Animals: 3 M

Observation Period: 21 days

Remarks – Method: One animal was killed humanely after 9 days due to the severity of the response. A minor protocol deviation (animals 41 weeks old at the commencement of the study instead of 12-40 weeks) was deemed unlikely to have an adverse impact on the study.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect#*	*Maximum Value at End of Observation Period#*
	1	2	3			
Conjunctiva – Redness	2.7	2.7	3.0	3	< 14 d	0
Conjunctiva – Chemosis	2.0	2.3	3.3	4	< 14 d	0
Conjunctiva – Discharge	2.0	2.0	3.0	4	< 14 d	0
Corneal Opacity	1.3	1.7	2.7	3	< 14 d	0
Iridial Inflammation	1.0	1.0	1.0	1	< 14 d	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal
#Based on two animals only.

Remarks – Results

The following effects were noted during the observation period: slight to moderate corneal opacity, slight iritis, very slight to severe conjunctival chemosis, slight to extensive mucoid discharge, and slight to diffuse beefy conjunctival redness. Hair loss on the right upper eye lid (2/3) was also noted in the animals during the observation period.

Translucent and 'nacreous' areas of opacity were evident in one animal from 48 hours after instillation and nine days after treatment an area of pannus formation was apparent in this animal. Due to the irreversible nature of the corneal findings in this animal, it was humanely sacrificed immediately after this examination and it was concluded that not all effects would be resolved by the end of the observation period.

CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	HLS (2011e)

B.4. Skin Sensitisation – LLNA

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2010) EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/Ca
Vehicle	Acetone/olive oil 4:1
Preliminary study	Yes, at 100%, 50%, 25%, 10% and 1%
Positive control	Hexylcinnamaldehyde (HCA)
Remarks – Method	No protocol deviations

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (SI) (test/control ratio)*
Test Substance			
0 (vehicle control)	4 F	637.73	-
1	4 F	774.44	1.2
2.5	4 F	2707.21	4.2
5	4 F	6616.08	10.4
Positive Control			
25	4 F	4438.26	7.0

EC3	1.9%
Remarks – Results	The highest concentration of 5% for the main test was chosen on the basis of the preliminary test, in which oedema was seen at 100% and an increase in ear thickness > 25% was seen at 100%, 50%, 25% and 10% but not at 1%. Erythema was not seen at any concentration. The highest concentration in the main study was chosen to be 5%. In the main study there were no deaths and no signs of systemic toxicity were observed in the test or control animals. Body weight change of test animals between day 1 and 6 was comparable to that noted in the corresponding control animals over the same period. A marginal weight loss in one animal at 2.5% was not considered significant. No dermal irritation was noted. Ear thickness was not measured. The SI obtained for 1, 2.5 and 5% w/v was 1.2, 4.2 and 10.4 respectively.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	HLS (2011f)

B.5. Repeat Dose Toxicity, with reproductive /developmental toxicity screening

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (1996)
Species/Strain	Rat/Crl:CD (SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: Males: premating period of 2 weeks and during mating (~5 weeks) for main phase;

	Females: premating period of 2 weeks and during mating, gestation and until day 6 of lactation for main phase. Also 5 weeks for unmated females for the toxicity phase. Dose regimen: 7 days per week
Vehicle	Propylene glycol
Remarks – Method	Three groups, each comprising of 10 male and 10 female rats for the main phase and 5 female rats for the Toxicity phase received the test substance by gavage at nominal doses of 10, 30 or 100 mg/kg bw/day. Dose levels were selected on the results of a 7-day preliminary study, in which dosing at 300 or 1,000 mg/kg led to bodyweight loss and multiple macroscopic changes in the gastrointestinal tract. No further details on this preliminary study were provided by the notifier. Analysis of the doses administered during the study showed discrepancy between the intended and actual achieved concentrations. The reason for the discrepancy could not be determined following several investigations. This and all other noted protocol deviations in the study report were not considered to have affected the integrity of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Nominal dose (mg/kg bw/day)*	*Mortality*
Control	10 M/15 F	0	0	0/20
Low Dose	10 M/15 F	10	7.1	0/20
Mid Dose	10 M/15 F	30	21.9	0/20
High Dose	10 M/15 F	100	75	3 F

Mortality and Time to Death

Three high dose females were found dead shortly after dose administration (day 14 and day 32). The oesophagus was found to be perforated in each of these females and the deaths concluded to be due to dosing error and not treatment-related.

Clinical Observations

Overall administration of the test substance was well tolerated at low and mid doses with no adverse effects on general condition, bodyweight gain and food consumption. Mean bodyweight gain was statistically significantly lower in high dose males (72% of control). Similarly, mean bodyweight gain was significantly lower in females at this dose during the first two weeks of treatment (67% of control) and during gestation. The study authors considered that the lower overall bodyweight gain during gestation may partly reflect the slightly lower litter size at this dose. Weight gain in dams during lactation was unaffected by treatment.

Lower motor activity scores for low and high dose animals were considered likely to be related to high scores in the control group, outside the historical control range and not treatment related. No statistically significant differences in forelimb or hindlimb grip strength values were observed in treated animals, compared to control animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Monocytes (white blood cells) and neutrophil counts were slightly higher in both males and females of the high dose group but the differences were only statistically significantly in males.

For clinical chemistry, a number of minor intergroup statistically significant differences were detected in various mean blood chemistry parameters. Creatinine was significantly increased in both males (high dose) and females (all doses) and plasma glucose levels were statistically significantly decreased in males of mid and high dose group. Similarly, total bilirubin and urea increased in males of mid and high dose groups and all dose groups, respectively. In females, statistically significant decrease in alanine aminotransferase (ALT) activity (low and mid dose groups) and total cholesterol (high dose group) and increase in aspartate aminotransferase (AST) activity, chloride and sodium in high dose group was observed. These effects were not considered by the study authors to be related to treatment as in most cases the differences were sex specific or showed no relationship to dose.

Effects in Parental Organs

There were no effects of treatment on organ weights in males following five weeks of treatment. In high dose females of the main treatment group, a trend towards lower adjusted mean kidney weight was observed on Day 7 of lactation. However, there was no macroscopic or histological correlation and the same effects did not occur in the toxicity phase female group. High dose females in the toxicity phase showed a statistically significant decrease in the adjusted mean thymus weight. There were no statistically significant weight changes in the other organs.

No organ weight changes related to treatment were reported in low or mid dose animals. Microscopic examination revealed foamy macrophages in the mucosa of the jejunum in 2 males and foamy histiocytes in the sinuses of the mesenteric lymph nodes in the majority of animals in mid dose group. Following five weeks of treatment at high dose, macroscopic examination revealed that the jejunum was thickened in all surviving animals; in some animals the mesenteric lymph nodes were enlarged and/or pale and/or had dark areas; the duodenum was thickened in 1 male and 2 females. Microscopic findings correlated with the macroscopic findings. Minimal foamy macrophages were identified in the mucosa of the duodenum in 2 females at high dose. The author states that dark areas seen in the mesenteric lymph nodes were probably due to sinus erythrocytosis and erythrophagocytosis, a common background finding.

Reproductive/developmental findings

Pre-coital interval, mating performance, fertility, gestation length, gestation index, and offspring survival and development were not affected by treatment at any dose. Oestrous cycle data showed an irregular cycle in one high dose female of the main test group. The number of implantations, litter size and percentage of live birth index were also lower in the high dose group, but the differences were not statistically significant. As the number of corpora lutea were not counted, it is not clear whether the changes were related to a low number of corpora lutea. The percentage of male pups in the high dose group was slightly higher than in controls, but was also not statistically significant. No treatment related macroscopic changes were found in the offspring.

Examination of the seminiferous tubules of the testes in parental males did not indicate any changes in the cells or the spermatogenic cycle.

Remarks – Results

The foamy macrophages in the mucosa of the jejunum and or/duodenum and foamy histiocytes in the sinuses of the mesenteric lymph nodes were considered by the study authors as either accumulation of the test substance or a metabolite in the macrophages in these tissues, or phospholipidosis. Since the cause of the foamy macrophages in the gut mucosa was uncertain this change was concluded to be potentially adverse.

CONCLUSION

The No Observed (Adverse) Effect Level (NOAEL) was established as 7.1 mg/kg bw/day for systemic toxicity in this study, based on the effects on the gastro-intestinal tract at 21.9 mg/kg bw/day. A No Observed Effect Level (NOEL) was established as 75 mg/kg bw/day for reproductive/developmental toxicity in this study, the highest dose tested.

TEST FACILITY	HLS (2010)

B.6. Genotoxicity – Bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Plate incorporation procedure
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA (pKM101)
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver (10% in Test 1 and 20% in Test 2)
Concentration Range in Main Test	Test 1 - 5 – 5,000 µg/plate Test 2 - 50 – 5,000 µg/plate
Vehicle	Ethanol

Remarks – Method

The dose selection for Test 2 was based on the toxicity observed in a preliminary test (reported as Test 1) carried out at 5 – 5000 µg/plate.

Positive controls:
With metabolic activation: 2-aminoanthracene (TA100, TA1535, WP2uvrA), benzo[a]pyrene (TA98, TA1537).
Without metabolic activation: 4-nitroquinoline-1-oxide (WP2 uvrA (pKM101)); sodium azide (TA1535, TA100); 9-aminoacridine (TA1537); 2-nitrofluorene (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	≥ 5,000	negative
Test 2		> 5,000	≥ 5,000	negative
Present				
Test 1	> 5,000	> 5,000	≥ 5,000	negative
Test 2		> 5,000	≥ 5,000	negative

Remarks – Results

No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any concentration of the test substance, either with or without metabolic activation.

The positive and negative controls gave 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

HLS (2011g)

B.7. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Directive 440/2008/EC B.10 Mutagenicity – *In vitro* Mammalian Chromosome Aberration Test

Species/Strain: Human
Cell Type/Cell Line: Lymphocyte
Metabolic Activation System: S9 mix from phenobarbitone/β-naphthoflavone induced rat livers
Vehicle: Ethanol
Remarks – Method: No significant deviations from the protocol.
S9 was used at 2% in test 1 and 5% in test 2

Vehicle and positive controls: without metabolic activation – mitomycin C; with metabolic activation – cyclophosphamide, were run concurrently with the notified chemical.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 15*, 16, 17, 18*, 19, 20, 21, 22, 23, 24, 25	3 h	21 h
Test 2	2.5*, 5, 7.5*, 10, 11, 12, 13, 14,15*, 16, 17, 18	21 h	21 h
Present			
Test 1	4.9*, 9.8*, 19.5*, 39.1, 78.1, 156.3, 312.5, 625, 1250, 2500	3 h	21 h
Test 2	5, 10, 15, 20, 25, 30*, 35*, 40, 45*, 50, 55	3 h	21 h

*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	-	≥ 18	≥ 1250	Negative
Test 2	-	≥ 15	> 18	Negative
Present				
Test 1	-	≥ 19.5	≥ 1250	Negative
Test 2	-	≥ 45	> 500	Negative

Remarks – Results

The test substance did not induce any statistically significant or dose related increases in the frequency of cells with chromosome aberrations either in the absence or presence of metabolic activation when compared with the vehicle control at any of the concentrations tested. The results were all within the range of historical solvent controls. The positive and vehicle controls provided a satisfactory response confirming the validity of the test system.

CONCLUSION

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

TEST FACILITY

HLS (2011h)

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 sludge
Exposure Period	28 days
Auxiliary Solvent	Tetrahydrofuran (THF)
Analytical Monitoring	Chemical Oxygen Demand (COD)
Remarks – Method	The Theoretical Oxygen Demand (ThOD) was not able to be calculated, therefore COD was used as the analytical monitoring method. After the study was completed the study sponsor supplied an idealised ThOD.

RESULTS

Test Substance			*Sodium benzoate*	
Day	*% Degradation (COD)*	*% Degradation (ThOD)*	*Day*	*% Degradation*
1	6	11	1	2
10	37	65	10	90
14	41	72	14	101
28	49	87	28	107

Remarks – Results	The following validity criteria were met. The reference test reached > 70% degradation by day 14 and pH was maintained between 7.3 and 7.5. Oxygen uptake in the inoculum blank was 17.07 mg O_2, which is slightly outside the expected range of 20 – 30 mgO_2, but within acceptable limits of < 60 mgO_2. The following validity criteria was not met: The Difference in extremes between replicates exceeded 20% (37 – 58% COD). This is likely due to the variable composition of the test substance and is not considered to have an impact on the overall validity of the test.
CONCLUSION	Based on the ThOD calculation, the test substance is readily biodegradable.
TEST FACILITY	HLS (2011b)

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	*Oncorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	168 mg $CaCO_3$/L
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	No deviations were noted. A limit test only was conducted. Due to the low water solubility of the test substance a WAF was prepared at the limit of solubility. TOC analysis was used to determine test concentrations due to the variable nature of the test substance.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0	0
100	8.27	10	0	0	0	1	1

LC50	>8.27 mg/L at 96 hours (WAF)
NOEC	8.27 mg/L at 96 hours (WAF)
Remarks – Results	The mortality in the test concentration was attributed to aggressive behaviour from other test subjects. All validity criteria were met, oxygen concentration was maintained at >60% of the air saturation value and analytical measurements were conducted to determine test concentrations.

CONCLUSION The test substance is not harmful to fish at the limit of its water solubility.

TEST FACILITY HLS (2012a)

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

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	270 mg $CaCO_3$/L
Analytical Monitoring	TOC
Remarks – Method	No deviations were noted. Due to the low water solubility of the test substance WAFs were prepared for the test concentrations.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
4.27	< LOD	20	0	0
9.39	0.121	20	0	0
20.7	0.096	20	9	18
45.5	0.168	20	17	20
100	0.194	20	20	20

LC50	15.2 mg/L at 48 hours (nominal)
NOEC	9.39 mg/L at 48 hours (nominal)
Remarks – Results	During the test, the temperature reached 22.4°C, which is outside the range 22 ± 2°C. This is not expected to have significantly impacted the study as this deviation was short and there were no anomalies in the control test group. All other validity criteria were met. The pH was maintained between 7.95 and 8.24 and the dissolved oxygen was maintained at > 3 mg/L. The LC50 is based on the nominal concentrations.

CONCLUSION The test substance is harmful to daphnia.

TEST FACILITY HLS (2012b)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0.298 - 100 mg/L Actual: 0.173 – 0.350 mg/L
Auxiliary Solvent	None
Analytical Monitoring	TOC
Remarks – Method	No deviations were noted. The temperature in the test briefly reached 24.2°C which is outside of the specified range of 21 – 24°C, additionally on days 0 and 1, the light intensity of the test area ranged from -13.6 to 19.3% which exceeds the ±15% threshold. Potassium dichromate was used as a positive control.

RESULTS

Biomass		*Growth*	
ErL50 (mg/L)	*NOEC (mg/L)*	*EbL50 (mg/L)*	*NOEC (mg/L)*
7.43	3.05	5.91	3.05

Remarks – Results	The protocol deviations are not expected to have a significant effect on the reliability of the test as all validity criteria for the control sample were met. The growth factor in the control sample was 18.9, the coefficient of variation was 4.64% and the average specific growth rate was 0.64%. The EbC50 of potassium dichromate was 0.776 mg/L which is within the expected range of 0.3 – 1 mg/L.
CONCLUSION	The test substance is toxic to algal growth.
TEST FACILITY	HLS (2012c)

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