File No: STD/1446

March 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Toner Pearls

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

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

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

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Director
NICNAS

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1446	Oce-Australia Ltd	Chemical in Toner Pearls	No	≤10,000 tonnes per annum	Component of ink

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

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

Environmental risk assessment
On the basis of assessed 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 ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the finished product:
  - Impervious gloves (if regularly performing printer maintenance operations)

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

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

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

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of ink, or is likely to change significantly;
- the amount of chemical being introduced has increased from 10,000 tonnes per annum, 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.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oce-Australia Ltd (ABN: 26 004 315 913)
Level 3, Building 1, 195 Wellington Road
CLAYTON VIC 3168

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual monomers, impurities, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

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

NOTIFICATION IN OTHER COUNTRIES
EU (2000)
USA (2008)
South Korea (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Crystalline diester compound
Oce Toner Pearls (contains notified chemical at ≤ 80% concentration)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC and, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	85-87 °C	Measured
Boiling Point	Decomposes without boiling from~243°C at 101.3 kPa	Measured
Density	1250 kg/m^3 at 20°C	Measured
Vapour Pressure	1.9x10^{-5} kPa at 20°C	Measured
Water Solubility	8.8 x 10^{-6} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected due to its limited solubility in water.
Partition Coefficient (n-octanol/water)	log Pow = 5.2 at 24.5 °C	Measured
Adsorption/Desorption	log K_{oc} = 4.7 at 35 °C	Measured
Dissociation Constant	Not determined	Does not contain readily dissociable functionalities.
Particle Size	Inhalable fraction (<100 μm): < 1% Respirable fraction (<10 μm): 0 %	Measured
Flash Point/flammability	Not highly flammable	Measured
Flammability	Not highly flammable	Measured
Flammability in Contact with Water	Not predicted to be flammable in contact with water	Estimated
Pyrophoric Properties	Not predicted to be pyrophoric	Estimated
Autoignition Temperature	> 400 °C	Measured
Explosive Properties	Not predicted to be explosive	Estimated
Oxidising Properties	Not predicted to be oxidising	Estimated

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

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured or reformulated in Australia. The notified chemical will be imported as a component of a finished product, in closed ink cartridges at ≤ 80% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 5000	< 5000	< 5000	< 5000	< 10,000

PORT OF ENTRY
Sydney (by sea and air)

TRANSPORTATION AND PACKAGING
The finished product (containing the notified chemical at ≤ 80%), spheres with about 12mm diameter, will be contained in polystyrene cartridges in sealed styrene-butadiene packaging. Each cartridge will contain either 500 g or 900 g of finished product. These cartridges will be packed in boxes. These will be packed in pallets and distributed within Australia by road.

USE
The notified chemical will be used as part of an ink for printing at ≤ 80% concentration. The finished product is only expected to be used in large format printers.

OPERATION DESCRIPTION
There will be no manufacture, reformulation or repackaging of the notified chemical in Australia.

End-use
The cartridges containing the finished product will be taken out of the blister package and placed into the printers. During this process, engineering controls will ensure that no ink falls out of the cartridge containers. During the printing process, the ink will pass through a spindle and fall into the imaging device in a closed system. Inside the printer the ink will be jetted onto the paper.

Almost all of the ink (> 98%) will be used for printing with the remainder (< 2%) ending as waste in a waste box. From time to time, contamination on the printer heads will be rinsed away with ink, which will also be collected in this waste box via a fully automated process. The waste material will be solid and stick to the bottom of the box with no direct contact to the user expected. This waste box will hold up to 300 g of waste. The user will remove the waste box and dispose of it to landfill.

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)*
Importation/waterside	< 8	10-50
Transport and storage	< 8	10-50
Office workers	Occasional	200
Service technicians	1	52

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the notified chemical as a component of the finished products at ≤ 80% concentration only in the event of an accidental rupture of containers.

End-use
Given the estimated low vapour pressure (1.9 x 10^{-5} kPa at 20 °C) of the notified chemical and the large size (12 mm) of the finished product, inhalation exposure to the notified chemical is not expected. As the finished product is contained within a sealed cartridge and the printing process is enclosed, the potential for dermal exposure will be limited during printing. However, service technicians and office workers may be dermally exposed to the notified chemical at ≤ 80% concentration on an infrequent basis when changing cartridges, removing waste boxes or during printer maintenance. Service technicians may wear gloves, though office workers are unlikely to do so.

Dermal exposure from contact with printed paper is not expected as the notified chemical will be bound to the paper matrix when printed.

6.1.2. Public Exposure
The finished ink product is expected to be used by office workers only in large format printers. Hence, public exposure is not expected during printing processes. The public may come into contact with the finished product containing the notified chemical at ≤ 80% concentration. However, the notified chemical is not expected to be bioavailable as the notified chemical will be bound to the paper matrix when printed.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL 150 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

Toxicokinetics, metabolism and distribution.
Whilst absorption of the notified chemical may occur (molecular weight < 500 Da),the extent of absorption through the skin or gastrointestinal tract is expected to be limited, based on its low water solubility (8.8 x 10^{-6} g/L at 20 °C) and relatively high log Pow(5.2 at 24.5 °C). While there are no data available on the metabolism of the notified chemical, hydrolysis of the notified chemical may occur.

Acute toxicity.
The notified chemical was found to be of low acute toxicity via the oral route with an LD50 >2000 mg/kg bw in rats. The notified chemical was also found to be of low acute dermal toxicity (LD50 >2000 mg/kg bw). Some signs of toxicity were observed in the study, with most animals showing signs of lethargy, hunched/flat posture and/orchromodacryorrhoea up to 6 days post-treatment (diarrhoea and ptosis were also reported in some males on days 1-2 post-treatment). Local effects, including erythema, scales and/or scabs were noted on the treated skin of most animals during the observation period.

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

Irritation and sensitisation.
The notified chemical was found to be non-irritating to the skin of rabbits and slightly irritating to the eyes of rabbits. The slight conjunctival effects that were noted in the eye irritation study resolved within 72 hours in all animals and were insufficient to warrant classification of the chemical as an eye irritant.

The notified chemical (5% induction concentration; 2% challenge concentration) was found not to be a skin sensitiser in guinea pigs under the conditions of the adjuvant skin sensitisation test.

Repeated Dose Toxicity.
In a 28 day repeat dose toxicity study in rats, the notified chemical was administered by oral gavage at doses of 50, 150 and 1000 mg/kg bw/day. No mortalities occurred during the study. The NOAEL was established by the study authors as 150 mg/kg bw/day based on the effects that were observed in animals treated at 1000 mg/kg bw/day. However, it is noted that there was uncertainty regarding whether the noted effects did actually represent adverse effects in response to treatment with the test substance. Noted effects included decreased mean body weight gain in high dose males and females (statistically significant for males on days 8 and 22 of treatment; no accompanied changes in feed consumption), increased motor activity recordings (3/5 high dose males and 2/5 high dose females, and 3/5 females treated at 150 mg/kg bw/day) and statistically significant deviations in clinical biochemistry parameters between the high dose females and the control animals (alanine aminotransferase activity and urea levels were significantly higher; no supportive microscopic lesions noted).

Mutagenicity/Genotoxicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an *in vitro* chromosome aberration test using human lymphocytes.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
There will be no reformulation or repackaging of the notified chemical in Australia. As such, only printer service technicians and office workers will be potentially exposed to the notified chemical at ≤ 80% concentration in finished products on an infrequent basis when changing cartridges, removing waste boxes or during printer maintenance. Gloves may be worn by service technicians if performing regular printer maintenance operations. Based on the toxicity studies provided, exposure to the notified chemical under the proposed use scenario is not expected to result in adverse health effects.

Therefore, based on the information available, the risk to workers associated with use of the notified chemical at ≤ 80% concentration in finished products is not considered to be unreasonable.

6.3.2. Public Health
Exposure of members of the public to the notified chemical during printing processes is not expected as the finished product containing the notified chemical is intended for use in printers in dedicated print rooms. Following printing onto paper (or other substrates), the notified chemical is not expected to be bioavailable. Therefore, under the proposed usage conditions, the risk to the public 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 finished product containing the notified chemical will be imported into Australia in closed cartridges. Therefore, no release of the notified chemical to the environment is expected during manufacturing and reformulation. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation as cartridges are designed to minimise release.

RELEASE OF CHEMICAL FROM USE
When used as an ingredient, the majority of the ink containing the notified chemical is expected to be applied to different paper or other media and fixed on the surface of the substrates. During printing, it is estimated < 2% of the total import volume of the notified chemical may be released to the environment as a result of ink waste. Collected waste ink residues are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Following its use, most of the notified chemical is anticipated to share the fate of printed articles and be

disposed of to landfill or subjected to paper recycling processes. Approximately half of the amount of used paper is expected to be recycled. Some of the notified chemical may partition to waste waters during paper recycling processes and be released to sewage treatment plants (STPs). Limited amounts of the notified chemical contained in empty cartridges are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The notified chemical as an ink ingredient is expected to remain fixed to paper for its useful life. The notified chemical is expected to be disposed of to landfill along with printed articles or released to sewer in recycling wastewaters when paper is recycled. During paper recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches to improve the detachment of ink from the fibres. Based on its low water solubility (8.8×10^{-6} g/L), high partition coefficient (log P_{ow} = 5.2) and adsorption coefficient (log K_{oc} = 4.7), the notified chemical is expected to partition to sludge during paper recycling and waste water treatment processes. The sludge is expected to be disposed of to landfill or applied to agricultural soils. A small proportion of the notified chemical may partition to the water column in STP effluent and be released to the aquatic compartment.

Based on its high n-octanol/water partition coefficient (Log Pow = 5.2), the notified chemical has potential to bioaccumulate,which is supported by the calculated bioconcentration factor (BCF) of 1253, using BCFBAF model, v3.01 (US EPA, 2011). However, due to the high potential for biodegradation (81% over 28 days), the notified chemical is unlikely to persist in the environment. In landfill, soils and water, the notified chemical is expected to degrade through biotic and abiotic processes to form water and oxides of carbon. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

For a worst case scenario, it is assumed that 50% of used paper is subjected to paper recycling with the associated waste water released to sewers over 260 working days, and that there is no removal of the notified chemical by STPs processes. The Predicted Environmental Concentration (PEC) is calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	5,000,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	19230.77	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	4,252	µg/L
PEC - Ocean:	425	µg/L

The above is a worst case calculation assuming no removal of the notified chemical from STPs. However, the expected partitioning to sludge was estimated by SimpleTreat (EC, 2003) to be 51%, and removal by degradation to be 31%. Based on this calculation, partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 21.68 g/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 144.57 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 722.87 mg/kg and 1445.75 mg/kg, respectively.

Based on the above mitigation calculation, the PEC values for the notified chemical in rivers and ocean were calculated to be 765.4 µg/L and 76.54 µg/L, respectively. However, the actual concentration of the notified chemical in surface water may be far below the PEC due to its low water solubility (8.8×10^{-6} g/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	LC50 (96 hours) > 0.03 mg/L	Not harmful to fish up to the limit of its water solubility
Daphnia Toxicity	EC50 (48 hours) > 0.038 mg/L	Not harmful to aquatic invertebrates up to the limit of its water solubility
Algal Toxicity	E_rC50 (72 hours) > 0.014 mg/L NOE_rC = 0.011 mg/L	Not harmful to algae up to the limit of its water solubility
Inhibition of Bacterial Respiration	EC50 (0.5 hours) > 100 mg/L*	Not inhibitory to microorganism respiration
Acute Earthworm toxicity	LC50 (14 days) > 1000 mg/kg*	Very slightly toxic to *Eiseniafetida*

* Based on nominal concentration of the test substance in the tests

The notified chemical is not considered to be harmful to aquatic life up to the limit of its water solubility, and under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) it is not classified for acute and long term hazard.

7.2.1. Predicted No-Effect Concentration

A PNEC for the aquatic compartment has not been calculated since the notified chemical is not harmful up to the limit of its solubility in water, based on the studies provided by the notifier.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated since the notified chemical is not harmful up to the limit of its water solubility. Whilst the notified chemical has the potential to bioaccumulate, it is not expected to persist in the environment due its potential to biodegrade. No unreasonable risk to the aquatic environment is expected from the notified chemical based on its reported use pattern and the absence of any significant acute toxicity effects to aquatic species.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 85-87°C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Determined by differential scanning calorimetry
Test Facility	NOTOX (2001a)

Boiling Point Decomposes without boiling from~243 °C at 101.3 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determined by differential scanning calorimetry
Test Facility	NOTOX (2001a)

Density 1250kg/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	Pycnometer method
Test Facility	NOTOX (2004a)

Vapour Pressure 1.9×10^{-5}kPa at 20°C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	No significant deviations from protocol.
Test Facility	NOTOX (2001b)

Water Solubility 8.8×10^{-6} g/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Column elution methods, HPLC analysis. No significant deviations from the protocol. Two test columns, each at two flow rates (ca. 24 and 12 mL/h). The aqueous samples were diluted 1:1 with acetonitrile prior to HPLC-UV analysis. In the chromatograms of the water samples, extra peaks were observed, but they did not interfere with the integration of the test substance peak. The extra peaks were derived from the impurities. The pH of the eluates ranged from 7.5 to 8.
Test Facility	NOTOX (2001c)

Partition Coefficient (n-octanol/water) log Pow = 5.2 at 24.5 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. No significant deviations from the protocol. A stock solution was prepared in methanol at a concentration of 910 mg/L. The stock solution was ultrasonicated for 15 minutes to completely dissolve the test substance. The test solution was prepared by 10× dilution of the stock solution with mobile phase.
Test Facility	NOTOX (2001d)

Adsorption/Desorption log K_{oc} = 4.7 at 35 °C

Method	OECD TG 121 Estimation of the adsorption coefficient (K_{oc}) on soil and on sewage sludge using HPLC
Remarks	No significant deviations from the protocol. A stock solution was prepared in acetonitrile at a concentration of 1100 mg/L. The stock solution was ultrasonicated for 5 minutes to completely dissolve the test substance. The test solution was prepared by 100× dilution of the stock solution with mobile phase. HPLC was performed at neutral pH considering that

the test substance is unlikely to be ionised at pH 5.5-7.5.

Test Facility NOTOX (2004b)

Particle Size

Method Manual Sieve and Laser Diffraction Particle Size Analysis, CTL SOP No.417 (internal method).

Volume %	100.0
Mean (µm)	452.1
Median (µm)	509.2
Mode (µm)	859.9
95 % Conf. limit (µm)	160-1270
S.D.	1.7
< 10% of material is	≤ 212.1 µm
< 25% of material is	≤ 333.5 µm
< 50% of material is	≤ 509.2 µm
< 75% of material is	≤ 688.8 µm
< 90% of material is	≤ 811.2 µm

Remarks Manual sieve analysis indicated that 43.5% by weight of the test substance had a particle size of < 850 µm. A subsequent laser diffraction analysis on the < 850 µm sample was performed, the results of which are given in the table above. The smallest particle size was ~ 48 µm with < 1% by volume of the test substance having a particle size < 100 µm.

Test Facility Chilworth (2004)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).

Remarks The test substance could not be ignited under the conditions of the test. The test substance melted in contact with the ignition source.

Test Facility NOTOX (2000a)

Flammability in Contact with Water Not predicted to be flammable

Method EC Directive 92/69/EEC A.12 Flammability (Contact with Water).

Remarks A statement provided by the testing laboratory indicates that the notified chemical does not contain chemical groups likely to lead to flammable gases in contact with water or damp air.

Test Facility NOTOX (2000b)

Pyrophoric Properties Not predicted to be pyrophoric

Method EC Directive 92/69/EEC A.13 Pyrophoric properties of solids and liquids.

Remarks A statement provided by the testing laboratory indicates that the notified chemical does not contain chemical groups likely to lead to spontaneous combustion in contact with air at room temperature.

Test Facility NOTOX (2000c)

Autoignition Temperature > 400 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.

Remarks The oven was increased from 20 °C to 400 °C at a rate of 0.5 °C/min. No self-ignition of the test substance was observed. After the experiment, the test substance had mostly evaporated leaving a small amount of grey residue which was collected in a container below the cube. This change in colour indicates that decomposition or reaction had occurred.

Test Facility NOTOX (2004c)

Explosive Properties Not predicted to be explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	The calculated oxygen balance for the notified chemical is -211%. This value is outside the region where there may be potential for explodability. The molecular structure does not contain any chemical groups that might lead to explosion.
Test Facility	NOTOX (2004d)

Oxidizing Properties Not predicted to be oxidising

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).
Remarks	A statement provided by the testing laboratory indicates that the notified chemical does not contain chemical groups that are expected to result in oxidising properties.
Test Facility	NOTOX (2004e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI (outbred, SPF-Quality)
Vehicle	Propylene glycol
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3F	2000	0/3
II	3M	2000	0/3

LD50	>2000 mg/kg bw
Signs of Toxicity	No signs of toxicity were observed.
Effects in Organs	No effects on organs were observed at the macroscopic level.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX (2000d)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar strain Crl:WI (outbred, SPF-Quality)
Vehicle	Propylene glycol
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5F/5M	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Erythema, scales and/or scabs were noted at the treatment site for most animals during the observation period.
Signs of Toxicity - Systemic	Lethargy, hunched/flat posture, and/or chromodacryorrhoea were noted in the majority of animals (up to day 6 post-treatment). In addition, diarrhoea and ptosis were reported to have been observed in some males on days 1-2.
Effects in Organs	Enlargement of the mandibular lymph nodes was noted in two males and two females. No other effects on organs were reported.
Remarks - Results	The dermal LD50 for the test substance was determined to be >2000 mg/kg bw

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

TEST FACILITY NOTOX (2004f)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The solid test substance was moistened with the vehicle prior to application.

RESULTS

Remarks - Results No skin irritation or signs of systemic toxicity were reported for any animal at any time point.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY NOTOX (2001f)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant protocol deviation. Following the 24-hour observation, a 2% fluorescein solution was instilled into both eyes of each animal.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.7	0.7	1	<72 hours	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Conjunctiva: discharge	0	0	0	1	<24 hours	0
Corneal opacity	0	0	0	0	<1 hour	0
Iridial inflammation	0	0	0	0	<1 hour	0

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

Remarks - Results Remnants of the test substance were noted in the treated eyes of the animals 1-hour post-instillation.

Instillation of the test substance resulted in slight irritation of the conjunctivae, which was seen as redness, chemosis and discharge. The irritation had resolved within 72 hours for all animals. No other signs of

eye irritation or damage were reported.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY NOTOX (2001g)

B.5. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation - Magnusson and Kligman guinea pig maximisation test.

Species/Strain Guinea pig/Dunkin Hartley Albino

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: <0.5%
topical: 2%

MAIN STUDY

Number of Animals Test Group: 10 F Control Group: 5 F

INDUCTION PHASE Induction Concentration:
intradermal: 2%
topical: 5%

Signs of Irritation Mild to well defined erythema was observed in all animals after the intradermal induction phase (similar results recorded for the control animals). Mild erythema was noted in 7/10 treated animals after the topical induction phase.

CHALLENGE PHASE

1st challenge topical: 2%

Remarks - Method No significant protocol deviations.

The test substance was mixed with 10% DMSO in corn oil as vehicle. The formulation was heated to 50°C during test substance preparation to facilitate the formation of a homogenate. The solution of the test substance was maintained in a water bath for an unspecified period of time prior to dosing.

Based on the results of the preliminary study, the maximum technically feasible/homogenous concentrations were determined to be 5%.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	2%	0/10	0/10
Control Group	2%	0/5	0/5

Remarks - Results No effects were observed in any animals in either the control or test group following the challenge phase.

A positive control study (using α-hexylcinnamaldehyde) had been previously conducted in the laboratory.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY NOTOX (2002)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/ Wistar strain Crl:WI (outbred, SPF-Quality)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28days Dose regimen: 7 days per week
Vehicle	Propylene glycol
Remarks - Method	No significant protocol deviations. The dosage levels were selected based on the outcomes of 5-day range-finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M/5F	0	0/10
low dose	5M/5F	50	0/10
mid dose	5M/5F	150	0/10
high dose	5M/5F	1000	0/10

Mortality and Time to Death
No mortalities occurred during the study.

Clinical Observations
In general, there were no treatment related clinical signs of toxicity reported.

Increased motor activity recordings were obtained for three high dose males and two high dose females, and three females treated at 150 mg/kg bw/day. However, the study authors noted that concurrent and similar changes of the low or high sensors were not always apparent and there were no supportive clinical signs of hyperactivity. Hence a relationship to treatment was considered by the authors to be uncertain.

Slightly lower total body weight gains were noted in both genders at the high dose. The weight gains of the high dose males were statistically significantly lower than those of the male control animals on Days 8 and 22. The changes in weight gain were not accompanied by concurrent changes in food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Blood analyses revealed slight deviations in clinical biochemistry parameters between the high dose females and the control animals (alanine aminotransferase activity and urea levels were statistically significantly higher). As there were no supportive microscopic lesions, a relationship of the deviations to treatment with the test substance was considered by the study authors to be uncertain. Statistically significantly lower total protein and albumin levels among males treated at 50, 150 and/or 1000 mg/kg bw/day were also noted and these were considered to be related to the slightly high control levels of these parameters (no-dose related trend was apparent).

A higher mean prothrombin time was noted in high dose males. As the value was considered to be within the normal range of values for this type of study and the control mean was slightly low, and as there was no histopathologic evidence of liver dysfunction, the change was considered by the study authors to be of no toxicological significance. In addition, the statistically significantly lower partial thromboplastin time in males treated at 50 mg/kg bw/day was not considered to be toxicologically significant as it occurred in the absence of a dose-response relationship.

Effects in Organs
No toxicologically significant observations were noted at necropsy.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established by the study authors as 150 mg/kg bw/day in this study, based on the observed effects at 1000 mg/kg bw/day.

TEST FACILITY NOTOX (2004g)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System S9fraction from Aroclor-1254 induced rat liver

ConcentrationRange in Main Test a) With metabolic activation: 3-333 µg/plate
b) Without metabolic activation: 3-333 µg/plate

Vehicle Dimethylsulphoxide (DMSO)

Remarks - Method No significant protocol deviations.

A preliminary test was performed from 3-5000 µg/plate with and without metabolic activation (strains TA100 and WP2uvrA). There was no significant increase in the number of revertant colonies with or without metabolic activation or any bacterial growth inhibition evident. Precipitation was observed in all strains at 333 µg/plate and above. The results of the preliminary test formed part of the main test (Test 1).

The negative control was DMSO and positive controls were sodium azide, 9-aminoacridine, daunomycin, methylmethanesulfonate, and 4-nitroquinoline-1-oxide in the absence of metabolic activation and 2-aminoanthracene in the presence of metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 333	≥333	Negative
Test 2		> 333	≥ 333	Negative
Present				
Test 1	> 5000	> 333	≥333	Negative
Test 2		> 333	≥ 333	Negative

Remarks - Results The test substance was tested up to the maximum dose level of 333 µg/plate. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies, with the exception of TA1537 in the presence of metabolic activation (Test 2). However, since this value was only just outside the limit of the historical range, the validity of the test was considered not to be affected.

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

TEST FACILITY NOTOX (2001g)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

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

Cell Type/Cell Line Human lymphocytes
Metabolic Activation System S9fraction from Aroclor-1254 induced rat liver
Vehicle Dimethylsulphoxide (DMSO)
Remarks - Method No significant protocol deviations.

A preliminary test was performed (3 hour exposure withmetabolic activation and 3, 24 and 48 hours exposure without activation) at concentrations 1-100 µg/mL. Precipitation was noted in the culture medium at 100 µg/mL, with the mitotic indices at this concentration ranging from 57-72.

The negative control was DMSO. Positive controls used in the study were Mitomycin C (without metabolic activation) and cyclophosphamide (with metabolic activation).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 33*, 100*	3	24
Test 2a	10*, 33*, 100*	24	24
Test2b	10*, 33*, 100*	48	48
Present			
Test 1	10*, 33*, 100*	3	24
Test 2	10*, 33*, 100*	3	48

*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	> 100	>100	≥ 100	Negative
Test 2	> 100	>100	≥ 100	Negative
Test2b	> 100	>100	≥ 100	Negative
Present				
Test 1	> 100	>100	≥ 100	Negative
Test 2		>100	≥ 100	Negative

Remarks - Results There was no significant increase in the number of aberrant cells in any cell line,either with or without metabolic activation.

The positive controls caused statistically significant increases in the proportion of aberrant cells, demonstrating 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 NOTOX (2004h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Chemical titration
Remarks - Method	No significant deviation from the protocol. The tests were conducted at a nominal concentration of 17.5 mg/L in duplicates. The test substance was not completely soluble to allow preparation of a concentrated solution of the test substance at a concentration of 1 g/L.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation($ThCO_2$)*	*Day*	*% Degradation($ThCO_2$)*
7	5	7	64
14	7	14	79
23	9	23	86
29	9	29	90

Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	NOTOX (2001h)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Silicone oil (2%)
Analytical Monitoring	Oxygen electrode
Remarks - Method	The test was performed according the guideline above with slight modification for the test concentration of the test substance. The tests were conducted at a nominal concentration of 0.75 mg/L for the test substance. The low concentration was used because of the poor water solubility of the test substance. The biodegradability was accurately measured as the biodegradation was not retarded by limited bioavailability in this test.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation(BOD/$ThCO_2$)*	*Day*	*% Degradation(BOD/$ThCO_2$)*
7	19	7	63
14	50	14	72
21	56		
28	81		

Remarks - Results	The degree of degradability at 28 days was determined to be 81%.

However, biodegradation of at least 60% was not reached within a 10-day window. Therefore, the notified chemical is not readily biodegradable.
All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not readily biodegradable

TEST FACILITY AKZO NOBEL (2004)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test - Static
Species Carp (*Cyprinuscarpio)*
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness 200 mg $CaCO_3$/L
Analytical Monitoring HPLC
Remarks – Method The test substance was not completely soluble in the test medium at a loading rate of 100 mg/L. In a limit test, a stock solution was prepared at 100 mg/L followed with 72 hours stirring. The resulting solution was clear and contained precipitate and a floating layer. The undissolved test substance was removed by filtration before being used for the test. A filtrate prepared at a loading rate of 100 mg/L was used for the limit test. The concentration of the test substance could not be maintained between 80-120% of the loading rate. However, the test concentration was maintained above water solubility throughout the test. Therefore, the test is considered to be valid.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control	< 0.002	7	0	0	0	0
100	0.03	7	0	0	0	0

LC50 > 0.030 mg/L at 96 hours.
Remarks – Results Concentration levels toxic to fish could not be reached up to the limit of its water solubility. All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to fish up to the limit of its water solubility

TEST FACILITY NOTOX (2004i)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia sp*. Acute Immobilisation Test - Static
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 250 mg $CaCO_3$/L
Analytical Monitoring HPLC
Remarks - Method The test substance was not completely soluble in the test medium at a loading rate of 100 mg/L. In a limit test, a stock solution was prepared at 100 mg/L, followed by 72 hours stirring. The resulting solution was clear

and contained precipitate and a floating layer. The undissolved test substance was removed by filtration before being used for the test. A filtrate prepared at a loading rate of 100 mg/L was used for the limit test. The concentration of the test substance could not be maintained between 80-120% of the loading rate. However, the test concentration was maintained above water solubility throughout the test. Therefore, the test is considered to be valid.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< 0.002	20	0	0
100	0.038	20	3	5

EC50 > 0.038 mg/L at 48 hours

Remarks - Results 25% immobilisation of daphnia was observed exposed to a test solution prepared at a loading rate of 100 mg/L. The average exposure concentration of the test substance was 0.038 mg/L. All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates up to the limit of its water solubility

TEST FACILITY NOTOX (2004j)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test - Static.

Species *Selenastrumcapricornutum*

Exposure Period 72 hours

Concentration Range Nominal: 8.8 µg/L, 10, 50 and 100 mg/L, 10 and 50% of 100 mg/L
Actual: 4.1, 11, 14, 6.8, 3.7 and 2.5 µg/L

Auxiliary Solvent Dimethylsulphoxide (DMSO)

Water Hardness 24 mg $CaCO_3$/L

Analytical Monitoring Microscope with counting chamber, spectrophotometric and HPLC

Remarks - Method The test substance was not completely soluble in the test medium at a loading rate of 100 mg/L. In a limit test, a test solution of 100 mg/L was prepared by stirring the mixture for 69 hours. The undissolved test substance was removed by filtration and the resulting solution was clear and colourless. The filtrate was used for the test.

An additional test was performed in order to determine if the observed toxicity was caused by the test substance itself or by the impurities. In the additional test, one test solution was prepared in DMSO to reach a concentration of 8.8 µg/L in test medium. Three test solutions of loading rate of 10, 50 and 100 mg/L were prepared individually as in the limit test. Two test solutions of 10% and 50% of 100 mg/L were prepared by serial dilution of the stock solution of loading rate of 100 mg/L.

The test was considered valid as it was conducted according to the guideline above without significant deviation from the protocol.

RESULTS

Biomass	*Growth*

E_bC50 mg/L at 72 h	NOE_bC mg/L	E_rC50 mg/L at 72 h	NOE_rC mg/L
> 0.014	0.011	> 0.014	0.011

Remarks - Results

Both cell growth and growth rate were not affected in solution where the initial concentration approached the water solubility.

In the limit test, 14% inhibition for algae cell growth rate was observed exposed to a test solution at a nominal concentration of loading rate of 100 mg/L. This could be partly due to the toxicity caused by the impurities in the test substance. The EC50 values for both cell growth and growth rate were above the water solubility.

CONCLUSION

The notified chemical is not harmful to algae up to the limit of its solubility.

TEST FACILITY

NOTOX (2004k)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test

Inoculum: Activated sludge

Exposure Period: 0.5 hours

Concentration Range: Nominal: 100 mg/L; Actual: Not reported

Remarks – Method: Conducted according to the guidelines above with no significant deviations from the protocol.

RESULTS

EC50: > 100 mg/L

Remarks – Results: No inhibition of respiration rate of the sludge was recorded at the loading rate of 100 mg/L. All validity criteria for the test were satisfied.

CONCLUSION

The notified chemical is not expected to inhibit microbial respiration

TEST FACILITY

NOTOX (2004l)

C.2.5. Acute toxicity to earthworm

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 207 Earthworms, Acute toxicity test

Species: *Eiseniafoetida*

Exposure Period: 14 days

Remarks – Method: Due to its limited solubility in water and acetone, the test media were prepared by mixing a measured amount of the test substance with 10 g quartz sand and subsequently mixing with the test medium. The actual concentration of the notified chemical was not calculated.

The test was conducted according to the guidelines above with no significant deviations from the protocol.

RESULTS

Concentration mg/kg		*Number of Earthworms*		
Nominal	*Actual*		*7 days*	*14 days*
control		40	0	0
1.0		10	0	2

10	10	0	0
100	10	0	0
1000	40	0	0

LC50	> 1000 mg/kg at 14 days
Remarks – Results	20% mortality was observed at the lowest concentration of 1.0 mg/kg. The mortality observed at the lowest concentration was assumed not to be substance related as no mortalities or other effects were observed in the control and other concentrations during the entire test. In addition, no differences in the body weight reduction between the control and the highest test concentrations for the test substance were observed. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is considered very slightly toxic to *Eiseniafetida*
TEST FACILITY	NOTOX (2011)

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