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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in KP01-C65

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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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FULL PUBLIC REPORT

Chemical in KP01-C65

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Océ Australia Limited (ABN 26 004 315 913)
Level 3, Building 1, 195 Wellington Road
CLAYTON VIC 3168

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Dissociation constant and Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan, EU, US, Korea, China.

2. IDENTITY OF CHEMICAL

Note: The notified chemical is a metal salt with organic ligands.

MARKETING NAME(S)
NB-10
KP01-C65 (contains the notified chemical at <10%)

MOLECULAR WEIGHT
Mn >500 Da.

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

3. COMPOSITION

DEGREE OF PURITY >98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Black crystalline powder

Property	Value	Data Source/Justification
Melting Point	Decomposed and/or reacted at >250°C	Measured
Boiling Point	Decomposed and/or reacted at >250°C	Measured
Density	1370 kg/m^3 at 20°C	Measured
Vapour Pressure	<1.47x10^{-11} kPa at 20°C	Measured
Water Solubility	< 2 ×10^{-5} g/L at 19.7°C	Measured
Hydrolysis as a Function of pH	Not determined	Hydrolysis is not expected to occur in the environmental pH range (4-9) under ambient conditions due to its low solubility in water
Partition Coefficient (n-octanol/water)	log Pow > 6.0 at 19.7°C	Measured
Adsorption/Desorption	log K_{oc} > 5.63 at 35°C	Measured
Dissociation Constant	Not determined	Could not be determined due to very low solubility in water
Particle Size	Inhalable fraction (<100 μm): 100% Respirable fraction (<10 μm): 100% MMAD* = 1.978 μm All particles were reported to be within the size of approximately 0.2 - 7 μm	Measured
Flash Point	Not determined	Expected to be high based on flammability
Flammability	Not highly flammable.	Measured
Autoignition Temperature	226°C	Measured
Explosive Properties	Not expected to be explosive	Structure contains no explosophores

* MMAD = Mass Median Aerodynamic Diameter

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

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported by sea as a component of finished ink toner products in powder form (<10% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.06	0.105	0.15	0.195	0.255

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 6 kg plastic toner bottles. It will then be transported by road to the notifier's warehouse for storage and subsequently to the printing facilities of customers or directly to customers.

USE
The notified chemical will be a component (<10%) of ink toner products (powder form) for use in paper printing.

OPERATION DESCRIPTION
The notified chemical will not be manufactured, reformulated or repackaged in Australia.

Ink bottles containing the notified chemical at <10% will be manually connected to the printing machine via an inlet and attached to a flexible tube that supplies the ink head. The ink will be automatically injected from the bottles into the printing machine.

While printers are running, printer operators may monitor their operation and keep the substrate (eg paper, etc) feeders stocked and attend to substrate jams.

After printing, the notified chemical will be bound with other ink ingredients into the substrate matrix.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Transport and warehousing
Workers are not expected to be exposed to ink products containing the notified chemical except in the event of an accident where the packaging is breached.

Printer operators
Printer operators are not expected to be significantly exposed to ink containing the notified chemical at <10%, as the printing process is mainly automated. However, dermal and accidental ocular exposure is possible to the notified chemical during the loading and replacement of ink bottles to the printing machine. During operation of the printers, inhalation exposure of workers may occur to dust of ink toner containing the notified chemical (<10%). However, such exposure is expected to be minimised by the use of dust masks.

Service technicians
Service technicians are expected to experience contact with ink containing the notified chemical at <10% during printer maintenance and the replacement of ink bottles. The most likely route of exposure is dermal. However, this is expected to be minimized by the use of gloves. Inhalation exposure may also occur but is expected to be minimised through the use of dust masks.

Handling of printed substrates
Substrates printed with ink containing the notified chemical (<10%), such as, books and promotional materials will be handled by workers. However, exposure is not anticipated for these workers, as the notified chemical will be bound within a print matrix and not bioavailable.

6.1.2. Public exposure
The public will handle paper printed with the notified chemical. However, once cured onto the paper, the notified chemical is expected to remain bound to the substrate print matrix. Thus, public exposure to the notified chemical is expected to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Inhalation toxicity	Not determined
Rabbit, skin irritation	non-irritating

Rabbit, eye irritation	non-irritating
Mouse, Local Lymph Node Assay (LLNA)	non-sensitising under conditions of the test
Rat, repeat dose oral toxicity – 28 days.	NOAEL >1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non-mutagenic
Genotoxicity – in vitro chromosome aberration	non-genotoxic

The notified chemical may be absorbed via the gastro-intestinal tract, perhaps by micellular solubilisation due to its high lipophilicity and low water solubility.

Dermal absorption is not expected to be significant due to its high molecular weight, high lipophilicity and low water solubility.

The notified chemical is of respirable (<10 μm) particle size and could be inhaled into the upper or lower respiratory tract including the tracheobronchial and pulmonary regions. Due to the low water solubility of the notified chemical smaller particles lodging in the tracheobronchial region are likely to be cleared by the mucociliary mechanism and swallowed. However, inhaled respirable particulates of the notified chemical lodging in the pulmonary region may not be readily cleared due to its low water solubility. There may be some potential for absorption across the respiratory tract epithelium due to its lipophilic nature. In summary, higher concentrations of exposure may be expected to result in increased impairment of clearance mechanisms (European Commission 2003, Chilworth Technology 2007).

The notified chemical was found to be of low acute oral toxicity.

The notified chemical was considered non-irritating to the skin and eye. Both tests reported slight effects immediately after treatment. However, these had resolved within 24 hours.

A local lymph node assay (LLNA) was conducted in mice at 10%, 20% and 40% concentration resulting in a stimulation index (SI) inversely proportional to the concentration. The study authors attributed this to the decrease in dermal absorption with increasing concentration of the notified chemical applied. Given that the SI did not exceed 3, the authors did not consider the notified chemical to be a skin sensitiser. However, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the National Toxicology Program Center for the Evaluation of Alternative Toxicological Methods (NICEATM) state: "A major failing of the LLNA… is its inability to identify metal salts as contact allergens." (p.25, ICCVAM, 1999). However, salts of the metal present in the notified chemical are not commonly identified as skin sensitisers. The notified chemical also contains ligands with chemical functionalities similar to known structural alerts for skin sensitisation (Barratt et al., 1994). In summary, the potential for the notified chemical to cause skin sensitisation cannot be ruled out entirely though it is not expected to be significant, particularly considering its expected low dermal absorption.

No significant treatment related effects were observed in a repeat dose oral toxicity study (28 days) in rats and therefore the NOAEL was established as >1000 mg/kg bw/day.

The notified chemical was found not to be mutagenic in an AMES test and non-clastogenic in an in vitro chromosome aberration test.

Health hazard classification
Based on the data provided, the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
There are no health hazards identified in the toxicological studies provided. However, the notified chemical may have skin sensitising potential. Workers will handle the bottles of ink containing the notified chemical at concentrations <10% during replacement of ink bottles, maintenance and cleaning. However, measures are expected to be in place in order to reduce the potential for exposure (dermal, ocular and inhalation), such as automated processes and the use of PPE including dust masks to lower potential inhalation exposure to dusts of ink toner containing the notified chemical. Provided these measures are in place, the potential for dermal and inhalation exposure will be low.

In summary, the risk to workers associated with handling of the notified chemical is not considered to be unacceptable under the conditions described.

6.3.2. Public health

The inks containing the notified chemical at <10% will not be sold to the public. The public will make dermal contact with dried printed materials. However, the notified chemical will be bound within the print matrix and is not expected to be bioavailable. Therefore, risk to the public from the notified chemical is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The product containing the notified chemical will be imported into Australia in containers for end-use, and will not undergo any further reformulation. Therefore, no environmental release is expected apart from accidental spills during transport or handling accidents.

RELEASE OF CHEMICAL FROM USE

Under normal use conditions, environmental release of the notified chemical from the ink bottles is not expected. In the case of spills, it is expected that the notified chemical will be physically contained and either swept or vacuumed up and subsequently disposed of to landfill.

Once the notified chemical is applied to paper, the majority of the notified chemical is expected to remain fused to the paper or trapped within the print. Approximately half of the paper to which the notified chemical will be bound within the print will eventually be disposed of to landfill with the other half expected to be recycled. In the case of recycling, the notified chemical may be released in effluent from the de-inking process.

Residues left in empty ink bottles (estimated to be less than 1% total import volume) are expected to be recycled or reused along with all residual toner in the recycling process. Spent ink bottles that are not recycled are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that the spent ink bottles containing residual notified chemical will either be disposed of to landfill or recycled. Notified chemical may also be disposed of to landfill indirectly from waste paper containing the notified chemical via recycling.

7.1.2 Environmental fate

Notified chemical applied to paper as a component of ink will be bound within the print matrix and is not expected to be bioavailable. The majority of the notified chemical is expected to be disposed of to landfill where it will slowly degrade by biotic and abiotic processes to form water and oxides of carbon, nitrogen and iron.

Approximately half of the paper to which the ink containing the notified chemical is applied will be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents that enhance detachment of ink from the fibres. Due to its very low solubility in water and high partition coefficient, very little of the notified chemical is expected to partition to the supernatant water that will be released to the sewer. Notified chemical associated with sludge generated through the recycling process is expected to be disposed of to landfill.

The notified chemical is not readily biodegradable, however, it is not anticipated to bioaccumulate due its high molecular weight.

For the details of the environmental fate study, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

PECs (ocean and river) have been calculated assuming that all of the imported notified chemical will be

applied to paper and half of this amount will be recycled. In this worst-case scenario it is assumed that the notified chemical will be released in recycling effluent from the de-inking process, that there would be no removal of the notified chemical by sewage treatment plants (STPs) and that release of the notified chemical will occur over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	255	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	127.5	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.49	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.12	µg/L
PEC - Ocean:	0.01	µg/L

The notified chemical is likely to be significantly removed from STP influent due to partitioning to sludge. However, for this worst-case scenario it is assumed the notified chemical is released to the environment only in STP effluent. STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.116 µg/L may potentially result in a soil concentration of approximately 0.7725 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.862 µg/kg and 7.725 µg/kg, respectively.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 > 0.044 mg/L	Not harmful up to the limit of its solubility in water
Daphnia Toxicity (48 h)	EC50 > 0.0416 mg/L	Not harmful up to the limit of its solubility in water
Algal Toxicity (72 h)	E_rC50 > 0.102 mg/L	Not harmful up to the limit of its solubility in water
Inhibition of Bacterial Respiration (3 h)	IL50 > 100 mg/L	Not harmful up to the limit of its solubility in water

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified chemical is classified as not harmful to algae, aquatic invertebrates, fish up to the limit of its solubility in water. Based on the absence of adverse acute effects up to the limit of its solubility in water, the notified chemical is not classified for long-term hazard.

7.2.1 Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was calculated using the acute endpoint for daphnia (EC50(48 h) > 0.0416 mg/L). An assessment factor of 100 was used since the endpoints of three trophic levels are available for the notified chemical.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 Aquatic Invertebrates	> 0.0416	mg/L
Assessment Factor	100	
PNEC:	> 0.416	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following risk quotients (Q=PEC/PNEC) have been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.12	> 0.416	< 0.279
Q - Ocean	0.01	> 0.416	< 0.028

The risk quotients for the worst-case scenario release have been calculated to be < 1 for both river and ocean compartments. The calculated risk quotients are an upper limit as the notified chemical is not expected to reach ecotoxicologically relevant concentrations due to its low solubility in water. The notified chemical is therefore not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided, the notified chemical is not classified as hazardous according to 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 unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable 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 a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers:
  - Respiratory protection (if dust exposure is expected).

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

- Service personnel should ensure adequate ventilation is present when removing spent ink toner bottles containing the notified chemical and during routine maintenance and repairs.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must 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.

Transport and Packaging

- Keep only in the original container.

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 particle size range of the notified chemical has intentionally changed to include particles of 0.1 μm (= 100 nm) or less in size.

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of an industrial ink toner product at < 10%, or is likely to change significantly;
- the amount of chemical being introduced has increased from 255 kg, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet
The MSDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point Decomposed and/or reacted at > 250ºC

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential scanning calorimetry. Decomposed and/or reacted at 250 - 290ºC. An endothermic peak was observed, however, it was shown not to be due to the melting of the test substance.
Test Facility	NOTOX (2007a)

Boiling Point Decomposed and/or reacted at >250ºC

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Differential scanning calorimetry. Decomposed at 250 - 290ºC
Test Facility	NOTOX (2007a)

Density 1370 kg/m^3 at 20ºC

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Gas comparison stereopycnometer
Test Facility	NOTOX (2007b)

Vapour Pressure <1.47×10^{-11} kPa at 20ºC

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Isothermal thermogravimetric effusion method
Test Facility	NOTOX (2007b)

Water Solubility < 2×10^{-5} g/L at 19.7°C

Method	OECD TG 105 Water Solubility EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Column Elution Method. In a preliminary test the water solubility of the substance was found to be < 10^{-2} g/L therefore the column elution method was chosen for the main study. The test substance (512.2 mg) was added to THF and mixed with 5 g LiChroprep Si 100 25-40 µm column material. The THF was completely evaporated at 50°C using a rotary evaporator. A column was filled with carrier material and enclosed by 0.5 µm frits. After the column was filled with double distilled water the system was allowed to equilibrate and stabilise for approximately 17 hours. The flow was then adjusted to 24 mL/hour and ten consecutive samples of 2 mL were taken. The flow was decreased to 12 mL/hour and again ten consecutive samples of 2 mL were taken. The column was eluted overnight with double distilled water at a flow rate of 6 mL/hour. The following day, five consecutive samples of 2 mL were taken at this flow rate. All samples were diluted 1:3 (v:v) with acetonitrile and analysed. In all samples the concentration of test substance was found to be below the limit of detection (2×10^{-5} g/L) by HPLC-UV.
Test Facility	NOTOX (2007a)

Partition Coefficient (n-octanol/water) log Pow > 6.0 at 19.7°C

Method	In house method based on OECD TG 107 Partition Coefficient (n-octanol/water)
Remarks	Three aliquots between 571 and 574 mg of the test substance were weighed into separate containers, to which 10 mL n-octanol was added to each container. The solutions were magnetically stirred at 19.7°C for 24, 48 or 72 hours. After stirring duplicate samples were taken from each container and centrifuged twice for 5 min at 25,658 × g at 20°C. A 100 µL aliquot was taken from the octanol phase and diluted to a volume of 25 mL with

acetonitrile. The solutions were further diluted to obtain concentrations within the calibration range. The test substance concentration was determined by HPLC. The concentration of test substance was observed to decrease with increasing stirring time and this was attributed to a reaction product forming between the test substance and octanol. However, since the octanol solubility of the test substance was much greater than its water solubility, the study was considered to be reliable. The Pow was calculated as the quotient of the octanol solubility (20.7 g/L) and water solubility (< 0.02 mg/L).

Test Facility NOTOX (2007a)

Adsorption/Desorption log K_{oc} > 5.63 at 35°C

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)

Remarks HPLC analysis was conducted at neutral pH at which the test substance is ionised. A stock solution of test substance (1192 mg/L) was prepared in THF. The test solution was prepared by adding 100 µL of stock solution to a 10 mL volumetric flask and making it up to the mark with mobile phase (55/45 (v/v) methanol/Milli-Q water). The test substance was shown to elute after the reference substance (2,4–DDT) retention time of 7.73 minutes. Hence the test substance had a K_{oc} greater than the reference substance.

Test Facility NOTOX (2007b)

Particle Size MMAD = 1.978 µm

Method Laser diffraction particle size analyser

Range (µm)	*Mass (%)*
<0.674	10
<1.689	50
<3.350	90
<7	100

Remarks All particles were reported to be within the size range of approximately 0.2 - 7 µm

Test Facility Chilworth Technology 2007

Flammability Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).

Test Facility NOTOX (2007a)

Autoignition Temperature 226°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Test Facility NOTOX (2007b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.

Species/Strain	Rat/Wistar Crl:WI
Vehicle	Propylene glycol
Remarks - Method	No significant protocol deviations

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	Hunched posture was observed in all animals on Day 1. Uncoordinated movements were noted in 1 animal on Day 1 and piloerection was observed in another animal on Day 1. All these clinical signs had resolved by Day 2. Black staining of the back in 4 animals was observed from Day 2 to Day 14. This was considered to be a result of the black colour of the notified chemical.
Effects in Organs	No adverse effects were reported during macroscopic examination.
Remarks - Results	Bodyweight gains of animals treated with the notified chemical were within the normal range for animals of this age and strain.

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

TEST FACILITY: NOTOX B.V. (2007c)

B.2. 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 Males
Vehicle	Ethanol/water (1:1)
Observation Period	72 hrs
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	<24 hrs	0
Oedema	0	0	0	0	0	0

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

Remarks - Results	Very slight erythema was observed in the treatment area of 1 animal which had resolved within 24 hours. Brown/black staining of the treated skin was observed throughout the study.

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

TEST FACILITY NOTOX B.V. (2007d)

B.3. 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 Males
Observation Period 72 hours
Remarks - Method No significant protocol deviations

RESULTS

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

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

Remarks - Results Redness and discharge was observed following treatment. This had resolved within 24 hours. Black staining of fur on the head and paws caused by the notified chemical was observed throughout the study, as were remnants of the notified chemical on the outside of the eyelids. However, no staining of ocular tissues was observed.

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

TEST FACILITY NOTOX B.V. (2007e)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/JNCrlj
Vehicle Acetone/Olive oil (4:1)
Remarks - Method No significant protocol deviations

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	319.2	-
10	317.8	1.00
20	223.5	0.70
40	121.2	0.38
Positive Control		
25%	1392.2	4.36

Remarks - Results	A slight body weight loss was observed in 3 animals on Day 6. However, in the absence of additional clinical signs, this was not considered to influence the results of the test. The notified chemical elicited a dose response inversely proportional to the concentration of the notified chemical. The study author's proposed that this was a result of the absorption decreasing with higher concentrations of the notified chemical. The positive control test found α-Hexylcinnanamaldehyde (HCA) to induce a stimulation index (SI) of 4.36 at 25% concentration, thus confirming the acceptability of HCA as a reliable positive control substance.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical under the conditions of the test. However, it is uncertain whether the test conditions employed would adequately detect the skin sensitisation potential of the notified chemical (due to the nature of the chemical).
TEST FACILITY	Mitsubishi Chemical Safety Institute Ltd (2006a)

B.5. Repeat dose toxicity – Based on translated summary of original study report

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	1% Tween 80 solution
Remarks - Method	Recovery group animals continued for 14 days following the 28 day dosing period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5/sex	0	0
low dose	5/sex	50	0
mid dose	5/sex	250	0
high dose	5/sex	1000	0
control recovery	5/sex	0	0
high dose recovery	5/sex	1000	0

Mortality and Time to Death

No mortalities were reported.

Clinical Observations

Black coloured faeces were observed in all treated animals throughout the treatment period of the study. A decrease in motor activity at time 0-10 mins was observed in females treated at 250 mg/kg bw/day. However, in the absence of any significant changes in other treated animals this was not considered to be of toxicological significance. No significant adverse findings related to sensory reactivity to stimuli, body weight or food consumption were reported.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Decreased mean corpuscular haemoglobin concentration was observed in males treated at 1000 mg/kg bw/day. Increases in mean corpuscular volume and mean corpuscular haemoglobin were reported in males treated with 250 mg/kg bw/day. In recovery males treated at 1000 mg/kg bw/day, a decreased blood cell count and increased mean corpuscular volume and mean corpuscular haemoglobin were reported.

The variations in haematological parameters observed in males were not considered to be adverse in the absence of a dose response or adverse effects in organs.
No adverse findings in clinical chemistry parameters or urinalysis were reported.

Effects in Organs
A decrease in absolute brain weights was observed in females treated at 250 and 1000 mg/kg bw/day. Decreases in absolute and relative thymus weights and increases in absolute and relative ovary weights were reported in females treated at 50 mg/kg bw/day.
Increases in absolute heart and adrenal weights were observed in recovery males treated at 1000 mg/kg bw/day.
At necropsy, black discolouration of the contents of the gastro-intestinal tract was noted in 4 males and 2 females treated at 50 mg/kg bw/day as well as all animals treated at 250 and 1000 mg/kg bw/day. This was not observed at the end of the recovery period.
The variations in organ weights were isolated and in the absence of a dose response or further significant findings, were not considered to be adverse effects related to treatment.

Remarks – Results
Isolated changes were observed at histopathological examination, including in control animals. However, no significant adverse findings were reported in any of the treatment groups.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established by the study author as >1000 mg/kg bw/day in this study, based on the absence of any toxicologically significant effects at this dosage level.

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (2007b)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	Phenobarbitone/5,6-benzoflavone-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	Positive controls: i) without S9: 2-(2-Fury)-3-(5-nitro-2-furyl)acrylamide (TA100, TA98), sodium azide (TA1535), 9-aminoacridine hydrate (TA1537) and N-ethyl-N'-nitro-N-nitrosoguanidine (WP2uvrA$^-$); ii) with S9: 2-aminoanthracene.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	-	≥313	Negative
Test 2	-	-	≥313	Negative
Present				
Test 1	-	-	≥313	Negative
Test 2	-	-	≥313	Negative

Remarks - Results No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum

dose of 5000 µg/plate, either with or without metabolic activation.

The positive controls confirmed the validity of the test system.

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

TEST FACILITY Japan Oilstuff Inspectors' Corporation (2006)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain Chinese Hamster
Cell Type/Cell Line Chinese Hamster Lung (CHL/IU)
Metabolic Activation System Phenobarbitone/5,6-benzoflavone-induced rat liver (S9 homogenate)
Vehicle Dimethyl sulfoxide (DMSO)
Remarks - Method Mitomycin C (without S9) and Benzo[α]pyrene (with S9) were used as positive controls.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	156, 313, 625*, 1250*, 2500*, 5000*	6 hrs	24 hrs
Test 2	156, 313, 625*, 1250*, 2500*, 5000*	24 hrs	24 hrs
Present			
Test 1	156, 313, 625*, 1250*, 2500*, 5000*	6 hrs	24 hrs

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>1250	≥156	Negative
Test 2	>1250	≥156	Negative
Present			
Test 1	-	≥156	Negative

Remarks - Results For Test 1 without metabolic activation, a small but statistically significant increase in the frequency of cells with numerical aberrations was noted in plates treated at 2500 and 5000 µg/mL. Similarly, statistically significant increases were noted in Test 2 following 24 hour exposure without metabolic activation in plates treated at 5000 µg/mL. In all cases, the increases were deemed by the study authors to be of no toxicological significance as they were within the historical control levels.

The positive and vehicle controls confirmed the validity of the test system.

CONCLUSION The notified chemical was not clastogenic to Chinese Hamster Lung Cells treated in vitro under the conditions of the test.

TEST FACILITY Japan Oilstuff Inspectors' Corporation (2007)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I)
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	HPLC, BOD and DOC
Remarks - Method	In accordance with the guidelines, the dissolved oxygen uptake of inoculated medium containing the test substance (100 mg/L) in completely filled closed bottles stored in the dark was measured over 28 days. A reference control (aniline, 100 mg/L) was run in parallel. Biodegradation was determined by measuring the oxygen depletion in the medium, corrected for the blank, and expressed as a percentage of the theoretical oxygen demand (ThOD: 70.8 mg/L). The test was conducted at 25°C.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation**	*Day*	*% Degradation*
7	0.23	7	60.6
14	0	14	69.2
21	0	21	70.7
28	0	28	71.2

*Mean of 3 replicates

Remarks - Results	All validity criteria for the test were satisfied. No deviations that may have affected the reliability of results were reported. The degradability results were calculated from the BOD measurements.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Mitsubishi Chemical Safety Institute Ltd (2007a)

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	*Oryzias latipes* (Medaka)
Exposure Period	96 hours
Auxiliary Solvent	N,N-dimethylformamide (100 µL/L)
Water Hardness	30 - 100 mg $CaCO_3$/L
Analytical Monitoring	LC/MS
Remarks – Method	Following a range finding test, a definitive test was performed as follows. One concentration of test substance (nominally 0.0450 mg/L) was prepared by dissolving stock solution (test substance and N,N-dimethylformamide) in dilution water (dechlorinated tap water) by stirring for 10 min. The fish were introduced to the test solution and maintained at 23.5 – 24.1°C under semi-static conditions for 4 days (pH 7.1–7.7, 6.0-8.3 mg O_2/L), and were observed for mortality and sub-lethal effects. A control (dilution water only) and solvent control (dilution water

and 100 µL/L N,N-dimethylformamide) were run in parallel to the main test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control	0	10	0	0	0	0
Solvent control	0	10	0	0	0	0
Test material						
0.0450	0.0440	10	0	0	0	0

LC50 > 0.0440 mg/L at 96 h

Remarks – Results All validity criteria for the test were satisfied and no mortalities were observed. No deviations that may have affected the reliability of results were reported.

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

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (2006b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Semi-static

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent 100 µL/L N,N-dimethylformamide

Water Hardness 49 mg $CaCO_3$/L

Analytical Monitoring LC/MS

Remarks - Method Following the range finding test a definitive test was performed. One concentration of test substance (nominally 0.0450 mg/L) was prepared by dissolving stock solution (test substance and N,N-dimethylformamide) in dilution water (dechlorinated tap water) by inversion. The daphnia were observed for immobilisation over two days (test conditions: artificial light dark cycle of 16h light to 8h dark, 20.0 – 20.2°C, pH 8.1–8.3, 8.4–8.8 mg O_2/L). A control (dilution water only) and solvent control (dilution water and 100 µL/L N,N-dimethylformamide) were run in parallel to the main test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	0	20	0	0
Solvent control	0	20	0	0
Test material				
0.0450	0.0416	20	0	0

EC50 > 0.0416 mg/L at 48 hours

Remarks - Results All validity criteria for the test guideline were satisfied and no immobilisation of daphnia was observed. No deviations that may have affected the reliability of results were reported.

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

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (2006c)

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: 0.210 mg/L
Actual: 0.102 mg/L (time weighted mean)
Auxiliary Solvent N,N-dimethylformamide (100 µL/L)
Water Hardness 0.24 mmol Ca^{2+} and Mg^{2+}
Analytical Monitoring LC/MS
Remarks - Method A range finding test was performed. One concentration of test substance (nominally 0.210 mg/L) was prepared by dissolving test substance and N,N-dimethylformamide in dilution water (dechlorinated tap water) for 10 min. Algae with a density of 5×10^3 cells per mL were exposed to test material at a nominal concentration of 0.210 mg/L. The test mixtures were irradiated at pH 8.0-9.3 and 23 ± 2°C for a period of 72 hours. A control (dilution water only) and solvent control (dilution water and 100 µL/L N,N-dimethylformamide) were run in parallel to the main test. The NOEC values were determined by Student's t-test, subsequent to F test for homogeneity of variances.

RESULTS

Biomass		*Growth*	
E_bC_{50} mg/L at 72 h	*NOEC mg/L*	*E_rC_{50} mg/L at 72 h*	*NOEC mg/L*
>0.102	>0.102	>0.102	>0.102

Remarks - Results No deviations that may have affected the reliability of results were reported. The concentration of the test substance decreased to 23% of the nominal concentration by the end of the test. Toxicity endpoints were therefore based on the time weighted average concentration.

CONCLUSION The notified chemical is not harmful to algae up to its limit of solubility in water

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (2006d)

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 3 hours
Concentration Range Nominal: 100 mg/L
Actual: Not determined
Remarks – Method Synthetic sewage feed (16 mL) and activated sludge (200 mL) were stirred for 24 h and added to test substance mixture which had been stirred in Milli-RO water for at least 24 h. Milli-RO water was added to make up a final volume of 500 mL and a test substance loading of 100 mg/L. The mixture was aerated during the contact time (3 h). After contact time the sample contents were poured into an oxygen bottle and the O_2 consumption was measured for approximately 10 minutes during

	which time the sample was magnetically stirred. The procedure was repeated with a duplicate and two controls were tested which contained no test substance. Reference material (3,5–dichlorophenol) at concentrations of 1.0, 3.2, 10, and 32 mg/L was used in order to confirm the suitability of the inoculum. The test water had a hardness of 1.44 mmol/L Ca^{2+} and 3.60 mmol/L Mg^{2+}.
RESULTS	
IC50	> 100 mg/L (based on nominal concentration)
Remarks – Results	All validity criteria for the test were satisfied. The EC50 of the reference material was in the accepted range and hence indicated the suitability of the inoculum.
CONCLUSION	The notified chemical has no significant inhibitory effect on microbial respiration up to its limit of solubility in water
TEST FACILITY	NOTOX (2007f)

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