File No: LTD/1608

October 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

E-BK105

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1608	Epson Australia Pty Ltd	E-BK105	Not determined	≤1 tonne per annum	Colourant in inkjet printer 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).

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

Hazard classification	*Hazard statement*
Acute Category 3	Harmful to aquatic life

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the 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 implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin and eye contact
  - Do not generate aerosols
  - Clean up spills promptly

- Service personnel should wear impervious gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs.

- 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(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- the notified chemical is imported in any form other than as a component of sealed ink-jet cartridges of capacity 100 g or less;
- further information becomes available on the genotoxicity potential of the notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a colourant in inkjet printing ink, or is likely to change 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 (M)SDS of the notified chemical provided by the notifier was 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)
Epson Australia Pty Ltd (ABN 91 002 625 783)
3 Talavera Road
North Ryde NSW 2113

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants 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)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
E-BK105

MOLECULAR WEIGHT
>1,000 Da

ANALYTICAL DATA
Reference UV-Vis, FTIR, HPLC-UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: black powder

Property	Value	Data Source/Justification
Melting Point/Boiling Point	Decomposition observed from 275 °C	Measured
Density	1680 kg/m^3 at 20 °C	Measured
Vapour Pressure	Not determined	As the notified chemical is a solid and has a high molecular weight, the vapour pressure is expected to be low
Water Solubility	≥ 507 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ > 1 year at 25 °C (pH 4, 7, 9)	Measured
Partition Coefficient (n-octanol/water)	log Pow < - 4.2 at 20 °C	Measured
Surface Tension	74.3 mN/m at 20 °C	Measured
Adsorption/Desorption	log K_{oc} < 1.3 at 35 °C	Measured
Dissociation Constant	Estimated pKa = 1.96-9.19	Calculated for the free acid form. The notified chemical is a salt which is expected to be ionised under environmental conditions.
Particle Size	Inhalable fraction (<100 µm): 55.96% Respirable fraction (<10 µm): 4.04% MMAD* = 110.75 µm	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	353 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Predicted negative	Contains no functional groups that would imply oxidising properties

* MMAD = Mass Median Aerodynamic Diameter

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. The notifier has advised that the notified chemical is not considered to be a self-reactive substance.

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 be imported as a component (up to 2%) of inkjet printer ink.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Epson Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of inkjet printer ink in sealed cartridges. Printer cartridges containing the notified chemical (at up to 2% concentration) will be transported within Australia (to/from warehousing facilities and retail outlets/end-users) by road.

USE
The notified chemical will be used as a component (up to 2%) of inkjet printing ink for commercial and household printers.

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

Following distribution of the imported ink containing the notified chemical (in the sealed cartridges) to end-use sites, printer service technicians, office workers and home users will open the packaging and insert the cartridges into the printers. When empty, the spent cartridges will be removed from the printer and disposed of.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	2	50
Warehouse workers	2-6	260
Printer technicians	8	260
Office workers	8	260

EXPOSURE DETAILS
During transport and storage, workers are unlikely to be exposed to the notified chemical (unless the packaging is breached).

Printer technicians and office workers may be exposed to the ink containing the notified chemical (up to 2%) when replacing used ink cartridges, clearing paper jams from the printer and during printer maintenance. Dermal exposure is expected to be the most likely route of exposure (accidental ocular exposure could also occur). However, given the design of the cartridges and the fact that workers would be aware of any exposure to the coloured ink, exposure to the notified chemical is expected to be limited if users follow the instructions for replacing spent cartridges.

Occasional dermal exposure during use of printers could also occur if the printed pages were touched before the ink had dried. Once the ink dries, the notified chemical will be bound to the paper matrix and is not expected to be bioavailable. Inhalation exposure to the notified chemical is not expected under the proposed use scenario.

6.1.2. Public Exposure

The public will use inkjet printer cartridges containing the notified chemical (up to 2%) for printing purposes at home. Exposure of these users to the notified chemical is expected to be of a similar or lesser extent than the exposure experienced by office workers.

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
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 >2.8 mg/L/4 hours; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 50 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration	Equivocal

Toxicokinetics, metabolism and distribution.

Absorption of the notified chemical across the gastrointestinal tract and the skin is expected to be limited by the high molecular weight (>1,000 Da) and the low partition coefficient (log P_{OW} <-4.2). However, bacterial skin microflora have been reported to be able to break down azo dyes into smaller species, which may be more readily absorbed (SCCNFP, 2002).

Given the coloured urine that was noted in oral toxicity studies (see below), it is likely that some absorption of the notified chemical across the gastrointestinal tract occurs following oral exposure.

Acute toxicity.

The notified chemical was found to be of low toxicity in acute oral and dermal toxicity studies in rats. In the acute oral toxicity study, evidence of the test substance in the urine was noted from day 2 to day 3-5.

The notified chemical was found to have low acute inhalation toxicity in a study in rats. Evidence of the test substance in urine was noted in both sexes from 2 hours to 2 days following exposure. Decreases in body weight gain were noted in animals of both sexes on day 2 with the animals noted to have gained weight on day 4.

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. In the eye irritation study, similar effects (*i.e.* slight conjunctival effects that cleared within 24 hours) were noted in the eyes of the rabbits that were washed and remained unwashed following instillation of the test substance.

There was no evidence of skin sensitization in an LLNA study in mice.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).

A NOEL of 50 mg/kg bw/day was established in a 28 day oral gavage repeated dose study in rats (at doses of 50, 250 and 1000 mg/kg bw/day, with a high-dose recovery group).

There were statistically significant low levels of sodium, potassium and chloride noted in animals of both sexes at dose levels of 250 and/or 1000 mg/kg bw/day. The statistically significant decreases in sodium and chloride levels persisted to the end of the recovery period in females treated at 1000 mg/kg bw/day.

Black discolouration of the kidneys and black content in the jejunum, ileum and/or cecum were observed at necropsy in both sexes treated at 1000 mg/kg bw/day at the completion of the treatment period, however, no matching histopathological changes were noted. In addition, slight hypertrophy of the kidney distal tubule and collecting tubule epithelia was noted in male and/or female animals treated at 250 and 1000 mg/kg bw/day. Slight squamous cell hyperplasia was also noted at the proventriculous border of the stomach in animals of both sexes treated at 250 and 1000 mg/kg bw/day. There was also a significant increase of globule leukocytes in the glandular stomach of both sexes receiving 1000 mg/kg bw/day. In general, these effects were evident in treated animals following the recovery period; however, the incidences were reduced compared to that of the dosing period.

Mutagenicity.
Azo dyes are a concern for their potential induction of mutagenicity and carcinogenicity. Liver azo reductase enzymes reductively cleave the molecule into component amines. This reduction may contribute to the carcinogenicity of many azo dyes. The notified chemical is not expected to be reductively cleaved to release any of the aromatic amines with carcinogenic potential listed in EU SCCNFP/0495/01 (SCCNFP, 2002). However, the notified chemical can be broken by azo reduction into a number of arylamine species, some of which could potentially be mutagenic.

The notified chemical was not mutagenic in a standard bacterial reverse mutation study and was not clastogenic in an in vitro mammalian chromosome aberration test under the conditions employed. The Ames test performed was a standard test, according to OECD Test Guideline 471. However, the test guideline strongly recommends the use of alternative procedures for the detection on mutagenicity of azo dyes, as it is recognised that the standard procedure may not be sufficiently sensitive for these chemicals. Modified tests are highly recommended as they utilise a reductive pre-incubation step before the test is carried out, which is considered to yield a greater detection of mutagenic azo dyes (Prival and Mitchell, 1982). As such mutagenicity of the notified chemical cannot be ruled out on the basis of the study performed.

The notified chemical showed equivocal results in an *in vitro* chromosomal aberration test. The study authors considered that a negative result had been obtained if both structural and numerical aberrant cells were observed at <5%. While none of the test systems had aberrations >5%, it is noted that at a concentration of 19.5 µg/mL (24 hour exposure; maximum concentration analysed), the number of cells with structural aberrations was 4.5% (cell growth index 47.7).

In addition, azo dyes are known to have impurities, including the presence of component arylamines (SCCNFP, 2002; Øllgaard, 1998). Such impurities are thought to contribute to their carcinogenicity, as these species may be more readily absorbed and activated as carcinogens. As such, these impurities may possibly contribute to the carcinogenicity potential of the notified chemical.

Overall, the genotoxic potential of the notified chemical cannot be ruled out, as one study showed equivocal results and reductive metabolism may be significant *in vivo*.

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
The notified chemical may be handled by workers at ≤2% concentration. Dermal exposure to the notified chemical may occur when replacing spent cartridges (and/or as incidental exposure when touching wet ink on printed pages). At these low concentrations, skin irritation is not expected. Toxicity arising from repeated exposure to the notified chemical cannot be ruled out but is not expected at the low proposed use concentrations (≤2%) and use in contained cartridges.

While significant dermal exposure of technicians to the notified chemical is not expected given its containment within cartridges, performing printer maintenance operations, in an industrial setting, may occur on a frequent basis. Therefore, measures should be taken to avoid exposure to the notified chemical (e.g. use of impervious gloves).

Dermal exposure of office workers to the notified chemical is expected to be infrequent and of a low level, given the containment of the chemical within cartridges and the provision of instructions for replacing the cartridges. There may be frequent exposure to dried ink containing the notified chemical, however, the chemical will be cured in the ink matrix and not be available for exposure.

Therefore, provided that measures to protect technicians are being adhered to (i.e., use of impervious gloves and adequate ventilation when performing printer maintenance operations), and based on the expected low exposure of office workers to the notified chemical, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Public exposure to the notified chemical is expected to be similar, though less frequent than that experienced by office workers. Therefore, the risk to the health of the public from use of the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of ink sealed in printer cartridges. No release of the notified chemical to the environment is expected due to manufacture, reformulation or repackaging as these activities will not occur in Australia.

RELEASE OF CHEMICAL FROM USE

During use, the notified chemical will be fixed within an inert ink matrix adhering to paper and is not expected to be released to the environment once cured. The spillage or leakage of ink during transport, use, installation or replacement will be contained with absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Following its use, the notified chemical is anticipated to share the fate of printed paper to be disposed of to landfill or subjected to paper recycling processes. Up to half the amount of the total import volume of the notified chemical may be released to sewage treatment plants when recycling waste water is disposed of to sewer. Residues of the notified chemical in empty cartridges (up to 2% of the total annual import volume) are expected to be disposed of to landfill along with the empty cartridges.

7.1.2. Environmental Fate

The notified chemical as a component of ink 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 paper or released to sewer in recycling wastewaters when paper is recycled. During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified chemical will partition to the supernatant water based on its high water solubility (>507 g/L), which is expected to be released to the sewer. During waste water treatment processes in sewage treatment plants (STPs), the notified chemical is not expected to be removed from waste water due to its water solubility and low soil adsorption coefficient (log Koc <1.3) and may be released to surface waters. The notified chemical is not readily or inherently biodegradable (<5% and <6% over 28 days, respectively) and hydrolysis is negligible at environmental conditions (>1 year at pH 4, 7 and 9). In landfill, the notified chemical is likely to be mobile based on its high water solubility and low soil adsorption coefficient (log Koc <1.3). However, the notified chemical is not expected to bioaccumulate due to the low n-octanol/water partition coefficient (log Pow <-4.2), high water solubility and molecular weight (>1000 Da). It is expected to eventually degrade by biotic and abiotic processes to form water, oxides of carbon, nitrogen and sulphur, and inorganic salts. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) can be estimated as outlined below assuming that 50% of annual import volume of the notified chemical will be released to sewage during recycling of the used paper. For the worst case scenario, it is assumed that the notified chemical is not removed from influent during STPs processes. It was assumed that release of the notified chemical occurs 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	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	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:	0.43	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.43 µg/L may potentially result in a soil concentration of approximately 2.84 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 14.17 µg/kg and 28.35 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 hours)	LC50 >99.3 mg/L	Not harmful
Daphnia Toxicity (48 hours)	EC50 >100 mg/L	Not harmful
Algal Toxicity (72 hours)	E_rC50 = 21.4 mg/L NOEC = 3.14 mg/L	Harmful
Inhibition of Bacterial Respiration	EC50 >100 mg/L	Not inhibitory to microorganism respiration

Based on the acute toxicity endpoint for algal, the notified chemical is formally classified as “Acute Category 3: Harmful to aquatic life” under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). One chronic toxicity endpoint for algae was available. Therefore, the long-term classification for the notified chemical was determined based on the most stringent outcome by comparing the long-term hazard classification using either the acute or chronic data. As there was determined to be no long term classification by either method, the notified chemical is therefore formally classified under GHS as “Not classified for long-term hazard”.

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species from the reported results is used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as the endpoints for three tropic levels are available. The acute toxicity endpoint for algae was used because it provides the lowest, most conservative PNEC value.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae).	21.4	mg/L

Assessment Factor	100	
PNEC:	214	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.43	214	0□002
Q - Ocean:	0.04	214	<0.001

The Risk Quotients (Q = PEC/PNEC) for the worst case scenario have been calculated to be <1 for the river and ocean compartments. Although the notified chemical may be released into waterways, it is unlikely to pose a risk to the aquatic environment due to the notified chemical's low ecotoxicity. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting/Boiling Point Decomposition observed from 275 °C

Method OECD TG 102 Melting Point/Melting Range
OECD TG 103 Boiling Point
Remarks Determined using differential scanning calorimetry. An exothermic effect was detected between 275 °C and 350 °C, which was determined to be due to reaction and/or decomposition of the test substance.
Test Facility NOTOX (2011a)

Density 1680 kg/m^3 at 20 ºC

Method OECD TG 109 Density of Liquids and Solids
Remarks Determined using a gas comparison stereopycnometer.
Test Facility NOTOX (2011a)

Water Solubility >507 g/L at 20 ± 0.5 ºC

Method OECD TG 105 Water Solubility
EC directive 440/2008, A.6 Water Solubility
Remarks Flask Method. One test sample was used for the water solubility determination of the notified chemical. The solution pH was 8.8.
Test Facility NOTOX (2011a)

Hydrolysis as a Function of pH $t_{1/2}$ >1 year at 25 ºC (pH 4, 7, 9)

Method OECD TG 111 Hydrolysis as a Function of pH
EC Directive 440/2008, C.7 Degradation-Abiotic Degradation: Hydrolysis as a Function of pH

pH	*T (°C)*	*t½ (years)*
4	25	>1
7	25	>1
9	25	>1

Remarks A preliminary test at 25 ºC in pH 4 and 7 showed less than 10% hydrolysis after 5 days. A main test at 50 ºC in pH 9 showed less than 10% hydrolysis after 13 days. This is equivalent to a half-life of >1 year at 25 ºC. The notified chemical had only 70% recovery in the test solution of pH 4, however, no explanation was provided for the loss of test substance. Tests were conducted in duplicate.
Test Facility NOTOX (2011a)

Partition Coefficient (n-octanol/water) log Pow <-4.2 at 20.1 ± 0.5 ºC

Method OECD TG 107 Partition Coefficient (n-octonal/water).
EC Directive 440/2008, A.8 Partition Coefficient (n-octonal/water)
Remarks Shake flask method. The pH of the aqueous phases was 7.1.
Test Facility NOTOX (2011a)

Surface Tension 74.3 mN/m at 20 ºC

Method OECD TG 115 Surface Tension of Aqueous Solutions
Remarks Determined using the OECD harmonised ring method (concentration: 1 g/L).
The test substance was considered not to be surface active.
Test Facility NOTOX (2011a)

Adsorption/Desorption – screening test log K_{oc} <1.3 at 35 ± 1 °C

Method OECD TG 121 Estimation of the adsorption Coefficient (K_{oc}) on Soil and on Sewage sludge using HPLC
EC Directive 440/2008,C.19 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using HPLC
Remarks The notified chemical eluted before the reference substance (log K_{oc} = 1.26). The log K_{oc} was concluded to be <1.3. The test was performed at neutral pH.
Test Facility NOTOX (2011a)

Dissociation Constant Expected to be ionised under environmental conditions

Method The notified chemical is a mixture of components, making direct measurement of its dissociation constants impractical. The notifier had provided pKa values for the free acid form of the notified chemical, calculated by the Perrin method, in lieu of measured values.
Remarks The notified chemical contains acidic groups with calculated pKa values of 2.3, 7.46 and 9.19, one basic group with a calculated pKa of 1.96.
The notified chemical is a salt which is expected to be ionised under environmental conditions.
Test Facility NOTOX (2011a)

Particle Size

Method ISO 13320:2009 Particle Size Analysis – Laser Diffraction Methods

Range (μm)*	*Mass (%)*
<272.97	90
<100.00	55.96
<85.44	50
<17.22	10
<10.00	4.04

*Mean of 5 measurements

Remarks The test substance was dispersed in silicone oil and analysed (over the range 0.02 μm to 2000 μm) 5 times using laser diffraction. The MMAD was 110.75 μm.
Test Facility Chilworth (2011)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks In the preliminary test, no propagation of combustion (200 mm length within 4 minutes) was observed.
Test Facility NOTOX (2011a)

Autoignition Temperature 353 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids
Remarks The test substance was heated in an oven at 0.5 °C/min and the temperature of the sample/oven measured using thermocouples. An exothermic event was noted at an oven temperature of 244 °C (temperature of the test substance reached 321 °C). A second exothermic event was observed at an oven temperature of 353 °C (temperature of the test substance reached 400 °C) and this was considered to be the autoignition temperature.
Test Facility NOTOX (2011a)

Explosive Properties Not explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties
Remarks Determined using differential scanning calorimetry (25-550 °C temperature program at a rate of 100 °C/min, under a flow of nitrogen). Exothermic decomposition was observed at 326 °C, with an exothermic decomposition energy of 350 J/g. Under the conditions of the

test, substances were considered to have explosive properties if the exothermic decomposition energy was greater than 500 J/g with an onset of decomposition below 500 °C. Therefore, the test substance was not considered to have explosive properties. The study authors noted that the sample chamber was swollen following the experiment.

Test Facility NOTOX (2011a)

Oxidizing Properties Predicted negative

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids)

Remarks The structure of the test substance was not considered to contain functional groups that would imply oxidising properties.

Test Facility NOTOX (2011a)

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/Crl:CD(SD)
Vehicle	Water
Remarks - Method	No significant protocol deviations A study on a similar chemical found an LD50 of 2000 mg/kg bw. Therefore the starting dose was set at 2000 mg/kg bw. This was the only dose tested.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	No animals died during the course of the study. Test substance in the feces was noted in all animals up to Day 3 or 4, and chromaturia (blackish) was observed in all animals from day 2 to day 3-5. These effects were attributed to the test substance.
Remarks - Results	There were no observable effects on body weights or noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	MCMC (2010c)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Crl:CD(SD)
Vehicle	Water
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations The test substance was applied to a lint cloth (lined with an impermeable sheet) that was moistened with water and the cloth applied to the skin.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity	There were no clinical signs observed in any animal
Remarks - Results	Decreased body weight was noted in one female at day 4, but weight recovered by day 8. There were no observable effects noted at necropsy.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	MCMC (2011a)

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test.
Species/Strain	Rat/Crl:CD (SD)
Vehicle	None
Method of Exposure	Nose-only
Exposure Period	4 hours
Physical Form	solid aerosol (particulate).
Particle Size	MMAD 4.7 µm after 1 hour exposure (40.0% particles <4 µm) MMAD 6.2 µm after 3 hours exposure (16.7% particles <4 µm)
Remarks - Method	Conducted using a flow-past nose only inhalation exposure chamber, where animals were restrained in tubes.

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
I	6M	4	2.8	0/6
II	6F	4	2.8	0/6

LC50	>2.8 mg/L/4 hours
Signs of Toxicity	Chromaturia (reddish brown) was noted in males and females from 2 hours to 2 days after exposure. Compound coloured stool was also noted in animals of both sexes on day 2.
Effects in Organs	There were no significant abnormalities noted in males or females at necropsy.
Remarks - Results	Decreases in body weight gain were noted in animals of both sexes on day 2 post-exposure. The animals were noted to have gained weight from day 4.
CONCLUSION	The notified chemical is of low toxicity via inhalation.
TEST FACILITY	MCMC (2011d)

B.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
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 test substance was moistened with water and applied to a patch, which was then applied to the skin.

RESULTS

Remarks - Results	There were no significant effects at any time point.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	MCMC (2010a)

B.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	96 hours
Remarks - Method	All animals received 0.1 g test substance in one eye. In 3/6 animals, the treated eyes were washed with 20 mL distilled water for 30 seconds, from 30 seconds after test substance administration. In the remaining 3/6 animals, the treated eyes remained unwashed. At the 24-hour observation, a 2% fluorescein solution was instilled into the treated eye 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	0	1	<24 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	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results	Slight effects on the conjunctivae were noted in all three rabbits at the 1 hour observation. These effects had reversed by the 24 hour observation. Similar conjunctivae effects were also noted in the 3 rabbits which had their treated eye washed following administration of the test substance.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	MCMC (2010b)

B.6. 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, v/v)
Remarks - Method	No significant protocol deviations. The maximum concentration tested (50%) was based on the absence of effects at 50% concentration (reported as the maximum feasible dose) in a preliminary study. Negative (vehicle) and positive control (α-hexylcinnamaldehyde; 25%) studies were run in parallel with the test substance.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1068.7	-

5	1215.5	1.14
15	852.3	0.80
50	800.7	0.75
Positive Control		
25	5724.7	5.36

Remarks - Results No signs of systemic toxicity were noted.

CONCLUSION Under the conditions of the test, there was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY MCMC (2010f)

B.7. Repeat dose toxicity

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/diet/drinking water
Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days
Vehicle Water
Remarks - Method No significant protocol deviations

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	250	0/10
high dose	5M+5F	1000	0/10
control recovery	5M+5F	0	0/10
high dose recovery	5M+5F	1000	0/10

Mortality and Time to Death
There were no deaths in any dose group during the study period.

Clinical Observations
Feces containing the test substance were noted in 2 males and 1 female treated at 50 mg/kg bw/day and in all animals treated at 250 and 1000 mg/kg bw/day from 2 days after initial dosing until 2 days post final dosing.

Increased mean body weights were noted in females treated at 1000 mg/kg bw/day (statistically significant from Day 29 onwards). Increased food consumption was also noted and was not considered by the study authors to be toxicologically significant.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Statistically significantly reduced sodium levels were noted in females dosed with 250 mg/kg bw/day and in both sexes treated at 1000 mg/kg bw/day. There was also low potassium levels observed in females treated at 1000 mg/kg bw/day (statistically significant) and low chloride levels in both sexes treated at 1000 mg/kg bw/day (statistically significant). The statistically significant decreases in sodium and chloride levels persisted to the end of the recovery period in females that received 1000 mg/kg bw/day.

Effects in Organs
Black discolouration of the kidneys and black content in the jejunum, ileum and/or cecum were observed at

necropsy in both sexes treated at 1000 mg/kg bw/day at the completion of the treatment period, however, no matching histopathological changes were noted. Following recovery, only the discolouration of the kidneys was evident in treated animals, and the incidence was reduced compared to that at the end of the dosing period.

Slight hypertrophy of the distal tubular epithelium of the kidney was noted in animals of both sexes treated at 250 and 1000 mg/kg bw/day and slight hypertrophy of the collecting tubule epithelium was noted in males treated at 250 mg/kg bw/day and in both sexes treated at 1000 mg/kg bw/day (statistically significant at 1000 mg/kg bw/day). These effects were also evident in treated animals following the recovery period, however, the incidences were reduced compared to that of the dosing period.

Slight squamous cell hyperplasia at the proventriculous border of the stomach was noted in both sexes treated at 250 and 1000 mg/kg bw/day (statistically significant at 1000 mg/kg bw/day). There was also a significant increase of globule leukocytes in the glandular stomach of both sexes receiving 1000 mg/kg bw/day (statistically significant in males). These effects were also evident in treated animals following the recovery period, however, the incidences were reduced compared to that of the dosing period.

There were no toxicologically significant, treatment related effects on organ weights.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 50 mg/kg bw/day in this study, based on the observation of adverse or toxicologically significant effects at doses of 250 and 1000 mg/kg bw/day.

TEST FACILITY MCMC (2011e)

B.8. 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	S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations A preliminary test was performed from 1.22-5000 µg/plate with and without metabolic activation. There was no significant increase in any revertant colonies with or without metabolic activation or any microbial growth inhibition evident. Precipitation was observed with metabolic activation in all strains at 313 µg/plate and above. Vehicle and positive controls (2-(2-Fury)-3-(5-nitro-2-furyl) acrylamide (AF-2), Sodium azide (NaN3), and 9-Aminoacridine hydrate (9-AA) without metabolic activation and 2-Aminoanthracene (2-AA) with metabolic activation) were used in parallel with the test material. The purity of the test substance was taken into account when preparing the solutions of the test substance.

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	>5000	>5000	Negative
Test 2		>5000	>5000	Negative
Present				

Test 1	>5000	>5000	≥313	Negative
Test 2		>5000	≥313	Negative

Remarks - Results: No significant increases in the frequency of revertant colonies were noted for any of the bacterial strains, either with or without metabolic activation.

The positive controls gave satisfactory responses, confirming the validity of the test system.

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

TEST FACILITY: GTRI (2010)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain: Chinese hamsters
Cell Type/Cell Line: Chinese hamster lung (CHL/IU)
Metabolic Activation System: S9 fraction from phenobarbital/5,6-benzoflavone induced rat liver
Vehicle: Saline
Remarks - Method: A preliminary toxicity study was performed (6 hour exposure, with and without activation and 24 hour exposure without activation) at concentrations 9.77-5000 µg/mL, with cytotoxicity evident from 9.77 µg/mL in the 24-hour exposure assay (based on the cell growth index).

Vehicle and positive controls (Mitomycin C without metabolic activation and Benzo [a] pyrene with metabolic activation) were used in parallel with the test material.

The purity of the test substance was taken into account when preparing the solutions of the test substance.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	625, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	2.44, 4.88*, 9.77*, 19.5*, 39.1, 78.1, 156, 313, 625	24 hours	24 hours
Present			
Test 1	625, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	625, 1250*, 2500*, 5000*	6 hours	24 hours

*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	>5000	>5000	>5000	Negative
Test 2	≥9.77	≥19.5	>625	Equivocal
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2		>5000	>5000	Negative

Remarks - Results: The study authors considered that a negative result had been obtained if both structural and numerical aberrant cells were observed at <5%. While

	none of the test systems had aberrations >5%, it is noted that for the 24 hour exposure, the number of cells with structural aberrations at the concentrations analysed was 0.5%, 3% and 4.5% at 4.88, 9.77 and 19.5 µg/mL, respectively (cell growth index 47.7 at 19.5 µg/mL), indicating a possible clastogenic effect of the test substance. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified chemical produced equivocal results for clastogenicity to Chinese hamster lung (CHL/IU) cells treated in vitro under the conditions of the test.
TEST FACILITY	MCMC (2010d)

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
Analytical Monitoring	Biochemical oxygen demand (BOD) Dissolved organic carbon measurement (DOC) HPLC
Remarks - Method	No significant protocol deviations.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	0	7	53
14	0	14	72
21	0	21	73
28	0	28	74

Remarks - Results	All validity criteria for the test were satisfied. The BOD, DOC and residual test substance amount measurements attained 0%, 5% and 0% degradation after 28 days, respectively. No transformation product was generated under the conditions of test.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	MCMC (2010g)

C.1.2. Inherent biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD Guideline for the Testing of Chemicals, 302B Inherent Biodegradability Zahn-Wellens EMPA Test
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC) Chemical oxygen demand (COD)
Remarks – Method	No significant protocol deviations.

RESULTS

Test substance		*Ethylene glycol*	
Day	*% Degradation(COD)*	*Day*	*% Degradation(COD)*
7	0	7	99.9
14	2.4	14	100.2
21	0	-	-
28	6	-	-

Remarks – Results	All validity criteria for the test were satisfied. The toxicity control attained 52.2% on the 14th day, thereby confirming that the test material was non-

toxic to sewage sludge micro-organisms.

CONCLUSION The notified chemical is not inherently biodegradable

TEST FACILITY Laboratory of Ecotoxicity & Environmental Safety (2011)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD
- Species: Medaka (*Oryzias latipes*)
- Exposure Period: 96 hours
- Auxiliary Solvent: None
- Water Hardness: 48 mg $CaCO_3$/L
- Analytical Monitoring: HPLC
- Remarks – Method: Following a range finding test, a limit test was conducted according to the guidelines above with no significant deviations from the protocol. Test solutions were changed every two days.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0	0
100	99	10	0	0	0	0	10

- LC50: >99.3 mg/L at 96 hours
- NOEC: Not determined
- Remarks – Results: One dead fish observed in the test solution was claimed not to be due to the test substance because the mortality was ≤10% and no abnormal symptoms were observed in other living fish. All other validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY MCMC (2011b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD
- Species: *Daphnia magna*
- Exposure Period: 48 hours
- Auxiliary Solvent: None
- Water Hardness: 234 mg $CaCO_3$/L
- Analytical Monitoring: HPLC
- Remarks - Method: Following a range finding test, a limit test was conducted according to the guidelines above with no significant deviations from the protocol.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 hours*	*48 hours*
0	-	20	0	0
100	100	20	0	0

- EC50: >100 mg/L at 48 hours

NOEC	Not determined
Remarks - Results	All validity criteria for the test were satisfied. No daphnia were observed floating on the surface of the water in any of test concentrations.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates
TEST FACILITY	MCMC (2011c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" (2006)
Species	Unicellular green algae (*Pseudokirchneriella subcapitata*)
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32 and 100 mg/L Actual: 0.95, 3.14, 9.86, 31.4 and 99.2 mg/L
Auxiliary Solvent	None
Water Hardness	~4.8 mg $CaCO_3$/L
Analytical Monitoring	Electric particle counter Microscope with a hemacytometer HPLC
Remarks - Method	Following a range finding test, the definitive tests were conducted according to the guidelines above with no significant deviations from the protocol.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 24 h	*mg/L*	*mg/L at 24h*	*mg/L*
Not determined	Not determined	21.4 (95% confidence limits: 20.7-22.2 mg/L)	3.14

Remarks - Results	All validity criteria for the test were satisfied. The percentage recovery of the nominal concentrations was between 95-99%. Experiments with liquid light transmission and with reduced light path were conducted to investigate the effect of the limitation of photosynthetic activity on the growth inhibition. The test was conducted under the conditions that reduced the effect of light attenuation to the extent possible. The inhibition of growth is very likely to have been influenced by the light absorbing properties of the notified chemical, but it cannot be concluded that algal growth has been inhibited solely as a reduction in light intensity. Therefore, the test substance is classified as harmful to algae.
CONCLUSION	The notified chemical is considered to be harmful to algae
TEST FACILITY	MCMC (2010e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test (1984).
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 100 mg/L

	Actual: Not determined
Remarks – Method	Conducted according to the guidelines above with no significant deviations from the protocol.
RESULTS	
EC50	>100 mg/L
NOEC	Not determined
Remarks – Results	All validity criteria for the test were satisfied. No significant inhibition of respiration rate of the sludge was recorded at 100 mg/L for the test substance. The IC50 of the reference substance 3,5-dichlorophenol is determined to be 7.0 mg/L.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration
TEST FACILITY	NOTOX (2011b)

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