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January 2009

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)**

# FULL PUBLIC REPORT

## CIM-06

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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**Director**
**NICNAS**

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# FULL PUBLIC REPORT

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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd (ABN 66 005 002 951)
1 Thomas Holt Drive NORTH RYDE NSW 2113

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, Other names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Purity, Use, Import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Flash point, Boiling point, Acute inhalation toxicity, *In vivo* genotoxicity, Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/744

NOTIFICATION IN OTHER COUNTRIES
US EPA PMN P-07-0661, August 2007
EU UK 07-06-2052-00, December 2007
Swiss SAEFL 07-41-0474-00, December 2007
Japan MOE, July 2008
Korea NIER 2007-460, January 2008
Philippines DENR PMPIN-2008-054, May 2008

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIM-06, C-C1, Cyan C-C1 Liq, Cyan C-C1

MOLECULAR WEIGHT
>500 Da

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

### 3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

ADDITIVES/ADJUVANTS None

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20ºC AND 101.3 kPa: Dark blue powder

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point | Decomposed without melting from 320ºC | Measured. |
| Boiling Point | Not determined | Not measured as notified chemical decomposed prior to melting |
| Density | 1770 kg/m$^3$ at 20ºC | Measured |
| Vapour Pressure | 3.2 x 10$^{-8}$ kPa at 25ºC | Measured |
| Water Solubility | 358-378 g/L at 20°C | Measured |
| Hydrolysis as a Function of pH | Stable (Half-life > 1 year) at pH 5, 7 and 9 | Measured |
| Partition Coefficient (n-octanol/water) | log Pow < -2.58 at 23ºC | Measured |
| Surface Tension | 71.9 mN/m | Measured |
| Adsorption/Desorption | log $K_{oc}$ < 1.25 at 30ºC | Measured |
| Dissociation Constant | Expected to be ionised in the environmental pH range (4–9) based on its structure | Estimated |
| Particle Size | Inhalable fraction (< 100 µm): 42.5%<br>Respirable fraction (< 10 µm): 2.61% | Measured |
| Flash Point | Not determined | The notified chemical is a high melting point solid. |
| Flammability | Not highly flammable | Measured |
| Autoignition Temperature | > 400ºC | Measured |
| Explosive Properties | Not explosive | Measured |
| Oxidizing Properties | Not oxidizing | Predicted based on the lack of oxidising chemical groups |

DISCUSSION OF PROPERTIES
Not expected to pose a physical hazard. For full details of tests on physical and chemical properties, please refer to Appendix A.

*Reactivity*
Not expected to be reactive under normal environmental and usage conditions.

## 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 (< 5%) of inkjet printer ink within ink cartridges.

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 Airport and Sydney Harbour

TRANSPORTATION AND PACKAGING
The ink cartridges will be transported by road to the notifier's warehouse for storage prior to distribution to office equipment retailers and offices nationwide. The size of imported ink cartridges is 55 mm x 10 mm x 25 mm - 225 mm x 45 mm x 150 mm and each cartridge will hold between 5-900 ml.

USE
The notified chemical is a component of inkjet printer ink for domestic and commercial use at a level of up to 5%.

OPERATION DESCRIPTION

The finished ink products are imported into Australia, and no local manufacture, reformulation or repackaging will be carried out. Sealed ink cartridges containing the notified chemical will be handled by service technicians, office workers or the public, who will replace spent cartridges in the printers as necessary. Office workers and public will use printers for varied printing work.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| *Category of Worker* | *Number* | *Exposure Duration* | *Exposure Frequency (days/year)* |
|---|---|---|---|
| Importation/ Waterside | 50 | < 8 hours/day | 10-50 |
| Storage and Transport | 15 | < 8 hours/day | 10-50 |
| Office worker/ consumer | 2,000,000 | 10 seconds/day | 2 |
| Service Technicians | 100 | 1 hour/day | 170 |

EXPOSURE DETAILS

Importation, waterside workers, storage and transport workers will only handle sealed cartridges containing the notified chemical and therefore exposure is not expected unless the packaging is accidentally breached.

Service technicians and office workers may experience dermal exposure to the ink containing up to 5% notified chemical when replacing used ink cartridges and repairing and cleaning ink jet printers. Workers are expected to be trained on safe and correct handling of cartridges to minimise exposure. Occasional dermal exposure to the ink may occur during normal use of the printer but the notified chemical will be dry and bound to the printed paper and not available for exposure.

#### 6.1.2. Public exposure

The ink cartridges will be available to the general public and home users may come into dermal contact to the ink containing the notified chemical (< 5%) when replacing used ink cartridges and handling printed paper in a manner similar to that of office workers. However home users are expected to handle ink cartridges and print less frequently, therefore exposure is expected to be less than that of 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 | $LD_{50}$ > 2000mg/kg bw, low toxicity |
| Rat, acute dermal toxicity | $LD_{50}$ > 2000 mg/kg bw, low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | severely irritating |
| Mouse, skin sensitisation – Local lymph node assay | no evidence of sensitisation up to 25% |
| Rat, repeat dose oral toxicity – 28 days. | NOAEL = 1000 mg/kg bw/day |
| Mutagenicity – bacterial reverse mutation | non mutagenic |
| Genotoxicity – *in vitro* chromosome aberration test | non genotoxic |

Acute toxicity

The notified chemical has low acute toxicity via the oral and dermal routes. Animals treated with a single high oral dose (2000 mg/kg bw/day) had dark livers and blue-stained kidneys at necropsy.

Irritation and Sensitisation

The notified chemical is non-irritating to rabbit skin and did not cause skin sensitisation when tested at 5, 10 and 25% concentration. In an acute eye irritation study in rabbits, treated eyes showed conjunctival redness,

chemosis and discharge, but all irritation symptoms resolved within 72 hours. Blue coloured staining of the cornea, nictitating membrane and lower conjunctival membrane was noted in treated eyes and did not fully resolve by the end of the 21-day study period. The notified chemical is considered severely irritating due to the persistence of eye colouration.

Repeated Dose Toxicity
The notified chemical primarily caused blue staining of the fur and excrement and discolouration of organs. Accumulation of pigment in the kidney, intestinal tract, lungs and lymph nodes were present in animals dosed at 150, 300 and 1000 mg/kg/day but it did not appear to cause adverse tissue reactions, inflammation or systemic toxicity in treated animals. The pigment continued to be present in tissues at the end of the study period. Haematology and urinalysis tests did not show any consistent changes that were indicative of toxicity. Microscopic changes were identified in the stomach; including secretion agglomeration and changes to the mucosa but these regressed during the recovery period. The NOAEL was considered to be 1000 mg/kg bw/day.

Mutagenicity
The notified chemical was not mutagenic to any bacterial strain in a bacterial reverse mutation test, and was not clastogenic to Chinese hamster lung cells in an *in vitro* mammalian chromosome aberration test.

***Health hazard classification***
Based on the eye irritation study, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi; R41 Risk of serious damage to eyes

### 6.3. Human health risk characterisation

#### 6.3.1. Occupational health and safety
Based on the available toxicological data, the notified chemical causes transient irritation and irreversible colouration of the eyes. However, the risk of eye exposure to service technicians and office workers is extremely low given that the sealed cartridge packaging and printing process is unlikely to lead to ocular exposure to the ink. The low concentration of the notified chemical within the ink (< 5%) further reduces the risk of potential eye damage from exposure. Office staff and service technicians may experience dermal exposure when replacing spent cartridges, clearing paper jams or during maintenance and servicing, but the notified substance is neither a skin irritant nor a skin sensitiser and direct exposure to the notified chemical is unlikely as it binds to the paper when dried. Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers.

#### 6.3.2. Public health
There is potential for widespread exposure to the public through home use of the printer ink when printing and replacing spent cartridges, similar to the exposure scenario for workers in occupational settings. But based on the relatively low proportion in the ink (< 5%), the reduced pattern of use and the type of packaging of the ink cartridge that minimises possible exposure, the notified chemical is unlikely to pose a significant risk to the public if the ink cartridges are used according to the instructions.

## 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 to Australia as a component of printer ink product in ready-to-use cartridges. No manufacturing or reformulation of the notified chemical will take place in Australia. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and will not be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. Workers at large businesses will undertake installation and replacement. If leakage or spillage does occur, the ink will be contained with absorbent material and disposed of to landfill in accordance with federal, state and local regulations.

Cartridges are contained within the printer until the contents are used up and then they are removed and sent for recycling or disposed of to landfill. Around 5% of the ink containing the notified chemical will remain in "empty" cartridges.

Most of the notified chemical (95%) will be bound to printed paper, which will be disposed of to landfill, recycled or possibly incinerated.

RELEASE OF CHEMICAL FROM DISPOSAL

Around 5 wt% of the ink containing the notified chemical will remain in "empty" cartridges. The notifier will collect the used cartridges by setting up the collection boxes in general merchandising stores and post offices, etc. The collected cartridges are sent to the subcontractor. The subcontractor disassembles the used cartridges and recycles as raw materials, for example as plastic material to be used to make plastic goods. The remaining ink separated from the used cartridges is disposed of under Australian regulations. The notifier will not recycle the used cartridges to be renewed as new cartridges by refilling the ink. The other cartridges which are not collected will be disposed of to landfill.

Printed paper, having the notified chemical thereon will be disposed of to landfill, recycled or possibly incinerated. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is re-pulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The wastes are expected to go to trade waste sewers. Approximately 50% (NOLAN-ITU 2001) of the ink printed on paper will enter paper recycling and a proportion of the ink is expected to be recovered during recycling by adsorption to sludge. Any chemical adsorbed to sludge during the recycling process will be disposed of to landfill.

### 7.1.2 Environmental fate

The majority of the notified chemical will enter the environment from disposal of paper products on which ink containing the notified chemical will be printed. During the printing, the notified chemical will be bound to the printed paper. Approximately 45% of the notified chemical will be disposed of to landfill by binding on the printed waste paper, and eventually degrade in-situ by abiotic and biotic processes into gases including water, hydrogen sulphide, ammonia, and oxides of carbon, sulphur and nitrogen. Free notified chemical in landfill may leach due to the low $K_{OC}$ and high water solubility.

The other 50% is expected to be released to sewer, after the deinking of paper during recycling. Assuming a worst case scenario, the entire amount of chemical from paper recycling will be released from sewage treatment plants into water environment.

The chemical is not readily biodegradable and not expected to bioaccumulate (for the details of the environmental fate studies please refer to Appendix C).

### 7.1.3 Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration arising from the industrial use pattern has been modelled for the worst case in which none of the notified chemical released in aqueous wastes from the recycling of paper is removed by; or degrades in, on-site waste water treatment and sewage treatment plants. As the notified chemical is to be used in industrial applications at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The details of the calculation based on these parameters are presented below

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | < 1000 | kg/year |
| Proportion expected to be released to sewer | 0.5 | |
| 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 | 200.0 | L/person/day |
| Population of Australia (Millions) | 21.374 | million |
| Removal within STP | 0% | |
| Daily effluent production: | 4,275 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | < 0.45 | µg/L |
| PEC - Ocean: | < 0.05 | µg/L |

### 7.2. Environmental effects assessment

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

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Fish Toxicity | LC50 > 100 mg/L | Not harmful |
| Daphnia Toxicity | EC50 > 100 mg/L | Not harmful |
| Algal Toxicity | $E_rC50$ > 100 mg/L | Not harmful |
| Inhibition of Bacterial Respiration | EC50 > 1000mg/L | Not harmful |

The notified chemical is not considered harmful to aquatic life based on the test results.

#### 7.2.1 Predicted No-Effect Concentration

The Predicted No Effect Concentration (PNEC) was calculated using the worst-case value for the acute toxicity to fish (LC50) and using a safety factor of 100 (data for three trophic levels of aquatic species were supplied).

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| LC50 (Fish) | > 100.00 | mg/L |
| Assessment Factor | 100.00 | |
| Mitigation Factor | 1.00 | |
| PNEC: | > 1,000.00 | µg/L |

### 7.3. Environmental risk assessment

| Risk Assessment | PEC µg/L | PNEC µg/L | Q |
|---|---|---|---|
| Q - River | < 0.45 | > 1000 | **< 0.01** |
| Q - Ocean | < 0.05 | > 1000 | **< 0.01** |

The Risk Quotient is less than 0.01 based on the worst-case prediction. Therefore, the notified chemical is not expected to pose a risk to the aquatic environment based on the current use pattern.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Xi; R41 Risk of Serious Damage to Eyes

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

| | *Hazard category* | *Hazard statement* |
|---|---|---|
| Serious Eye Damage/Eye Irritation | 1 | Irreversible effects on the eye/serious damage to eyes |

**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**

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:

  Xi; R41 Risk of serious damage to eyes

  S25 Avoid contact with eyes
  S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  S39 Wear eye/face protection

- Use the following risk phrases for products/mixtures containing the notified chemical:

  Conc ≥ 10%: R41
  5% ≤ concentration < 10%: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as used in printing inks:
  - Avoid contact with eyes
  - Printers should be located in well-ventilated areas;

- 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 by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by 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 notified chemical is imported in any fashion other than within an inkjet ink cartridge;
- the notified chemical is introduced in a solid form;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of inkjet printer ink, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1 tonne, 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 the 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/Freezing Point** Decomposed without melting at 320ºC

Method OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined by differential scanning calorimetry.
Test Facility SafePharm Laboratories (2007a)

**Density** 1770 kg/m$^3$ at 20ºC

Method OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a gas comparison pycnometer
Test Facility SafePharm Laboratories (2007b)

**Vapour Pressure** 3.2 x 10$^{-8}$ kPa at 25ºC

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance. No statistical analyses were performed because the balance readings were too low and variable for a line of best fit to have any meaning. A regression slope on a chosen data point was imposed to provide an estimate of the maximum value for the vapour pressure at 25ºC.
Test Facility SafePharm Laboratories (2007c)

**Water Solubility** 358-378 g/L at 20ºC

Method EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method with visual assessment
Test Facility SafePharm Laboratories (2007a)

**Hydrolysis as a Function of pH**

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

| *pH* | *T (°C)* | *Recovery after 5 days* |
|---|---|---|
| 4 | 50 | 98.2% |
| 7 | 50 | 98.7% |
| 9 | 50 | 100.5% |

Remarks HPLC analysis revealed < 10% hydrolysis, corresponding to half-lives > 1 year at 25ºC.
Test Facility SafePharm Laboratories (2007b)

**Partition Coefficient (n-octanol/water)** log Pow < -2.58 at 23ºC

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Shake Flask Method, performed at pH 7 as recommended for salts.
Test Facility SafePharm Laboratories (2007a)

**Surface Tension** 71.9 mN/m at 22ºC

Method EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 1.00 g/L, 0.964 g/L corrected for purity
Test Facility SafePharm Laboratories (2008a)

**Adsorption/Desorption** log $K_{oc}$ < 1.25 at 30°C
– screening test

Method OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks The test substance eluted from the HPLC column before the reference substance (formamide) used to determine the dead time of the column. This is probably due to ionisation of the test substance. The guideline requirement that measurement be carried out for ionised and unionised forms could not be met because of the presence of both acidic and basic functionality.
Test Facility SafePharm Laboratories (2007b)

**Dissociation Constant**

Remarks Testing was not carried out as the test substance is a complex mixture containing multiple acidic functionalities with overlapping pKas that are expected to be ionised in the environmental pH range (4–9).
Test Facility SafePharm Laboratories (2007b)

**Particle Size**

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

| *Range (μm)* | *Mass (%)* |
|---|---|
| < 100 | 42.5 |
| < 10 | 2.61 |
| < 5.5 | 0.459 |

Remarks The inhalable fraction (<100 μm) was determined by sieve. The fractions <10 μm and <5.5 μm were determined using a cascade impactor.
Test Facility SafePharm Laboratories (2007b)

**Flammability** Not highly flammable

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical failed to ignite during a 2 minute application of a Bunsen flame.
Test Facility SafePharm Laboratories (2007d)

**Autoignition Temperature** > 400ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The steel mesh cube contained black charred remains after the test.
Test Facility SafePharm Laboratories (2007c)

**Explosive Properties** Not explosive

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks BAM fall hammer test, BAM friction test and Koenen steel tube test were performed.
Test Facility SafePharm Laboratories (2007c)

**Oxidizing Properties** Not oxidizing

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Based on the chemical structure, the result for the oxidising properties has been predicted negative.
Test Facility SafePharm Laboratories (2007c)

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

## B.1. Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 420 Acute Oral Toxicity - Fixed Dose Method.<br>EC Directive 2004/73/EC B.1 *bis* Acute Toxicity (Oral) Fixed Dose Method. |
| Species/Strain | Rat/Sprague-Dawley |
| Vehicle | Distilled water |
| Remarks - Method | Only one high dose (2000 mg/kg bw) was tested using the Limit Test method. A total 5 female rats (1 in sighting study and 4 in main study) were given a single dose by gavage. |
| RESULTS | |
| LD50 | > 2000 mg/kg bw/day |
| Signs of Toxicity | No sign of systemic toxicity was observed in any animal in the sighting and main study and all animals showed expected bodyweight gains. |
| Effects in Organs | All animals had dark livers and blue-stained kidneys at necropsy. |
| Remarks - Results | Observations include blue-coloured staining of urine and faeces in four animals four hours after dosing and one and two days after dosing. On the third day, blue-coloured staining of the faeces was observed in one animal. All animals appeared normal (with no staining) by the fourth day. |
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |
| TEST FACILITY | SafePharm Laboratories (2007e) |

## B.2. Acute toxicity – dermal

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 402 Acute Dermal Toxicity.<br>EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal). |
| Species/Strain | Rat/Sprague-Dawley |
| Vehicle | Moistened with Arachis oil BP |
| Type of dressing | Semi-occlusive. |
| Remarks - Method | Only one high dose (2000 mg/kg bw) was administered on 5 female and 5 male rats using the Limit Test Method. |
| RESULTS | |
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity - Local | No sign of local adverse reactions was observed although purple-coloured staining was noted at all treatment sites one to three days after dosing. |
| Signs of Toxicity - Systemic | There were no signs of systemic toxicity. |
| Effects in Organs | No abnormalities were noted at necropsy. |
| Remarks - Results | There were no signs of dermal irritation or adverse reactions and all animals showed expected gains in bodyweight during the study period. |
| CONCLUSION | The notified chemical is of low toxicity via the dermal route. |
| TEST FACILITY | SafePharm Laboratories (2008b) |

## B.3. Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion.<br>EC Directive 2007/73/EC B.4 Acute Toxicity (Skin Irritation). |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | Moistened with distilled water |

| | |
|---|---|
| Observation Period | 72 hours |
| Type of Dressing | Semi-occlusive. |
| Remarks - Method | No significant protocol deviations. |

RESULTS

| | |
|---|---|
| Remarks - Results | There was no evidence of skin irritation in any animal (score 0). Blue-coloured staining was noted at all treated skin sites during the study. The study authors indicated that this colouration did not affect the evaluation of skin reactions. |
| CONCLUSION | The notified chemical is non-irritating to the skin. |
| TEST FACILITY | SafePharm Laboratories (2007f) |

### B.4. Irritation – eye

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 405 Acute Eye Irritation/Corrosion.<br>EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation). |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Observation Period | 21 days |
| 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* | 1.00 | 0.67 | 1.00 | 2 | < 72 hrs | 0 |
| *Conjunctiva: chemosis* | 0.33 | 0.33 | 0.67 | 1 | < 72 hrs | 0 |
| *Conjunctiva: discharge* | 0.33 | 0.33 | 0.33 | 1 | < 48 hrs | 0 |
| *Corneal opacity* | 0.00 | 0.00 | 0.00 | 0 | 0 | 0 |
| *Iridial inflammation* | 0.00 | 0.00 | 0.33 | 1 | < 48 hrs | 0 |

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

| | |
|---|---|
| Remarks - Results | Blue coloured staining of the fur was noted around all treated eyes throughout the study. Blue coloured staining was noted in two animals that covered the lower half of the cornea at the 24, 48, 72-hour and 7-day observations. In one animal, this corneal staining persisted to the 14-day observation and then reduced so that approximately one-quarter of the cornea was still stained at the 21-day observation. Blue coloured staining of the nictitating and lower conjunctival membrane was noted in two animals one hour after treatment and was present in all animals at the 24, 48, 72-hour and 7 and 14-day observations. Pale blue coloured staining of the nictitating membrane and lower conjunctival membrane was observed in all animals at the 21-day observation. |
| CONCLUSION | The notified chemical is considered severely irritating to the eye based on the persistence of colouration in the treated eyes. |
| TEST FACILITY | SafePharm Laboratories (2007g) |

### B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 429 Skin Sensitisation: Local Lymph Node Assay<br>EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay) |

| | |
|---|---|
| Species/Strain | Mouse/CBA/CaBkl |
| Vehicle | Ethanol/distilled water (7:3) |
| Remarks - Method | No significant protocol deviations. α-Hexylcinnamaldehyde (85%) was used as the positive control. The test substance did not dissolve in any of the other solvents recommended in the test guideline. 50% concentration of the test material did not result in a solution suitable for dosing and so 25% was chosen as the highest dose. |

RESULTS

| *Concentration (% w/w)* | *Proliferative response (DPM/lymph node)* | *Stimulation Index (Test/Control Ratio)* |
|---|---|---|
| *Test Substance* | | |
| 0 (vehicle control) | 392.91 | - |
| 5 | 461.32 | 1.17 |
| 10 | 551.55 | 1.40 |
| 25 | 774.41 | 1.97 |
| *Positive Control* | | |
| 5 | - | 2.64 |
| 10 | - | 8.36 |
| 25 | - | 12.94 |

| | |
|---|---|
| Remarks - Results | Blue-coloured staining on the ears and fur was observed on Day 2 and onwards in animals dosed with 25% test substance. Fur loss on the ears was also noted in these animals on Days 5 and 6. The positive control assay (using HCA in ethanol/distilled water (7:3)) was conducted approximately 2 years before the test substance assay. In addition, other more recent positive control assays with different control chemicals and vehicles (within 6 months of the test substance assay) have been conducted in the testing laboratory. The reliability of the test method is therefore considered to have been demonstrated. |
| CONCLUSION | There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical at a concentration up to 25% |
| TEST FACILITY | SafePharm Laboratories (2007h) |

**B.6. Repeat dose toxicity**

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.<br>EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral). |
| Species/Strain | Rat/Sprague-Dawley Crl:CD |
| Route of Administration | Oral – gavage |
| Exposure Information | Total exposure days: 28 days<br>Dose regimen: 7 days per week |
| Vehicle | Distilled water |
| Remarks - Method | Number of animals: 5 male and 5 female in each dose group.<br>Dose levels: 0 (control), 25, 150, 300, 1000 mg/kg bw/day.<br>A control recovery group and high-dose (1000 mg/kg bw/day) recovery group were maintained without treatment for a further 14 days after the end of the 28-day dosing period. |

RESULTS

*Mortality and death*

No deaths were recorded during the study.

*Clinical Observations*

Animals of both sexes treated with 150, 300 and 1000 mg/kg showed blue/dark staining on the cage tray liners and faeces throughout the study period. Females treated with 150 mg/kg and animals of both sexes dosed at 300 and 1000 mg/kg exhibited blue staining on the fur and tail. Recovery animals of both sexes treated with 1000 mg/kg/day continued to show staining of faeces and cage tray liners during their 14-day treatment-free

period. All test animals showed normal expected weight gain during the treatment period and no adverse effect on food consumption was observed.

*Functional and sensory reactivity observation*
There were no toxicologically significant changes in functional performance and sensory reactivity.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*
Females treated with 1000 mg/kg/day showed a statistically significant increase in lymphocyte count. A reduction in the mean cell haemoglobin concentration (MCHC) was also noted in females treated with 300 and 1000 mg/kg/day, however no effect was observed in males treated at the same dose. Males of all treatment groups had reduced plasma bilirubin levels but this was not observed in any female treatment groups. These changes were not consistent between the sexes and were not considered toxicologically significant.

Male and female rats treated with 150, 300 and 1000 mg/kg/day and one male treated with 25 mg/kg/day showed blue or green coloured urine. Recovery animals also produced green coloured urine during the 14-day treatment-free period. Urine colouring indicates that the test material or metabolites were being excreted.

*Effects in Organs*
**Organ weight** – No toxicologically significant changes were measured, but an increase in kidney weight was recorded in males treated with 1000 mg/kg/day.
**Necropsy** – No toxicologically significant changes to organs were observed. Discolouration was noted in the majority of tissues in both male and female animals treated with 150, 300 and 1000 mg/kg/day as well as animals in the recovery group after cessation of treatment.

*Histopathology*
**Kidney –** Accumulation of blue pigment was observed in the proximal tubular epithelium of nephrons in animals of both sexes treated with 300 and 1000 mg/kg/day and females treated with 150 mg/kg/day. Animals in the high-dose recovery group continued to show pigment accumulation after the end of the treatment period.
**Stomach** – Changes to the glandular stomach (agglomeration of mucosal secretion, mucous cell hyperplasia, mucosal basophilia and atrophy) were observed in animals of either sex treated with 1000 mg/kg/day and for males treated with 25, 150 and 300 mg/kg/day. Acanthosis and hyperkeratosis of the limiting ridge was also seen as an effort of treatment in animals of either sex treated with 1000 mg/kg/day and among males at the remaining dose levels. By the completion of the recovery (14-day) period, all observed conditions had regressed in the recovery group animals.
**Intestinal tract** – Blue pigment accumulation was observed in the lamina propria of the mucosa throughout the intestinal tract (except in the duodenum) of animals of either sex treated with 1000 mg/kg/day. In animals treated with 150 and 300 mg/kg/day, blue pigmentation was confined only to the jejunum. The high-dose recovery group animals continued to show pigment after the treatment had ceased, including the duodenum.
**Lungs** – Three males and two females treated with 1000 mg/kg/day as well as 1 recovery male and 2 recovery females treated at the same dose exhibited accumulation of blue pigment within alveolar macrophages. But the investigators could not determine whether the effect was due to inadvertent inhalation of the test material or a systemic effect, although aspiration appeared to be the more likely cause due to the pattern of distribution of the pigment. Two recovery females showed extensive areas of inflammation and macrophage infiltration that lead the investigators to suspect that a dosing error may have been the cause for the pigment accumulation. The observed lesions were not considered to be due to an adverse reaction to pigment accumulation.
**Cervical lymph node** – Blue pigment were seen in females treated with 1000 mg/kg/day and for 2 females treated with 300 mg/kg/day. Pigment accumulation regressed in the recovery group for female animals but 2 males within the group showed evidence of accumulation during the recovery period.
**Mesenteric lymph node** – Accumulation of blue pigment was seen in relation to males and females treated with 1000 mg/kg/day, and this persisted among the recovery group animals. Despite the presence of the pigment, there was no evidence of inflammation suggesting that the material does not elicit an inflammatory response after oral exposure.

RESULTS

Remarks – Results

Evidence of blue staining of the fur, faeces, urine and cage tray lining is not considered to be of toxicological importance as this is related to normal excretion of the blue-coloured test material and its metabolites. Pigment accumulation of the organs did not appear to cause adverse tissue reactions or inflammation although the pigmentation did persist in several organs and the long-term implications are unknown. The observed changes in the stomach and intestinal tract may have been related to irritancy and were not viewed as signs of toxicity

because the condition had resolved during the 14-day recovery period. Overall, the histopathological changes at 1000 mg/kg/day were not considered to be adverse health effects.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was considered to be 1000 mg/kg bw/day in this study.

| | |
|---|---|
| TEST FACILITY | SafePharm Laboratories (2008c) |

### B.7. Genotoxicity – bacteria

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test.<br>EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.<br>Plate incorporation procedure |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100<br>*E. coli*: WP2uvrA$^-$ |
| Metabolic Activation System | Rat liver S9 preparation (induced by phenobarbitone/β-naphthoflavone) |
| Concentration Range (Main Test) | With and without metabolic activation: 50, 150, 500, 1500, 5000 µg/plate |
| Vehicle | Distilled water |
| Remarks - Method | Positive controls: N-ethyl-N'nitro-N-nitrosoguanidine (WP2uvrA$^-$, TA100, TA1535), 9-Aminoacridine (TA1537), 4-Nitroquinoline-1-oxide (TA98). |
| RESULTS | |
| Remarks - Results | The test substance did not cause any visible reduction in the growth of bacterial colonies at any dose level either with or without metabolic activation in the preliminary and main test. No precipitate was observed on any plate at any dose. A blue colour was noted in all plates, particularly from 1500 µg/plate, however the colouration did not prevent the scoring of revertant colonies. No significant increase in the frequency of revertant colonies was observed for any bacterial strain, with or without metabolic activation at any dose. The positive controls induced expected increases in the frequency of revertant colonies, thus confirming the reliability of the test system. |
| CONCLUSION | The notified chemical was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | SafePharm Laboratories (2007i) |

### B.8. Genotoxicity – in vitro

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 473 In vitro Mammalian Chromosome Aberration Test.<br>EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test. |
| Cell Type/Cell Line | Chinese Hamster Lung (CHL/IU) |
| Metabolic Activation System | Rat liver S9 preparation (induced by phenobarbitone/β-naphthoflavone) |
| Vehicle | Eagle's Minimal Essential Medium (MEM) |
| Remarks - Method | Positive controls: Mitomycin C (cultures without metabolic activation), Cyclophosphamide (cultures with metabolic activation). A preliminary test was performed with doses ranging 0-5000 µg/mL at a 6-hour exposure (with and without metabolic activation) and 24-hour continuous exposure with metabolic activation. |

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 0*, 9.75, 19.5, 39, 78.1*, 156.25*, 312.5* | 6 hours | 24 hours |
| Test 2 | 0*, 19.5*, 39*, 78.1*, 156.25*, 312.5, 468.75 | 24 hours | 24 hours |
| *Present* | | | |
| Test 1 (5% S9) | 0*, 39, 78.1, 156.25, 312.5*, 625*, 1250* | 6 hours | 24 hours |
| Test 2 (2% S9) | 0*, 39, 78.1, 156.25*, 312.5*, 625*, 1250* | 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* | 312.5 | > 312.5 | > 468.75 | Negative |
| *Present* | 625 | 1250 | > 1250 | Negative |

Remarks - Results

In the 24-hour exposure group, cells exposed to concentrations at and above 312.5 µg/mL appeared blue and 'fixed', with the effect increasing in intensity with each increase in the dose concentration. The test material did not induce any statistically significant increases in the frequency of cells with aberrations at any concentration either with or without metabolic activation. The positive controls induced the expected increases in the frequency cells with aberrations, thus confirming the reliability of the test system.

CONCLUSION

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

TEST FACILITY

SafePharm Laboratories (2007j)

# 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 | On-site sludge sampling was carried out at the 10 locations in Japan. Return sludge, surface water and surface soil that were in contact with atmosphere were collected. |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | BOD and DOC, together with HPLC of unchanged test substance. |
| RESULTS | The following results are based on measurement of BOD. |

| *Test substance* | | *Aniline* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 7 | -2.3 | 7 | 56 |
| 14 | -3.3 | 14 | 73 |
| 21 | -2.3 | 21 | 77 |
| 28 | -1.6 | 28 | 79 |

| | |
|---|---|
| Remarks - Results | HPLC analysis recovered 98% of the test substance unchanged. |
| CONCLUSION | Not readily biodegradable. |
| TEST FACILITY | Kurume Laboratory (2007) |

### C.1.2. Bioaccumulation

Bioaccumulation was not tested as the notified chemical is a water soluble salt that would not be expected to bioaccumulate in fish.

## 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.<br>EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static. |
| Species | Rainbow trout |
| Exposure Period | 96 hours |
| Auxiliary Solvent | None |
| Water Hardness | 140 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC (LOQ 2.1 mg/L) |
| Remarks – Method | Limit tests were conducted at a nominal concentration of 100 mg/L which was confirmed by analysis. |
| RESULTS | |
| LC50 | > 100 mg/L at 96 hours. |
| NOEC (or LOEC) | 100 mg/L at 96 hours. |
| Remarks – Results | There was no mortality in the range finding test (single sample of 3 fish) or the definitive test (duplicate samples of 10 fish). No sublethal effects were observed. |
| CONCLUSION | Not harmful to fish. |
| TEST FACILITY | SafePharm Laboratories (2007k) |

### C.2.2. Acute toxicity to aquatic invertebrates

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.<br>EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static. |
| Species | *Daphnia magna* |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Water Hardness | 250 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC |
| Remarks - Method | Limit tests were conducted at a nominal concentration of 100 mg/L that was confirmed by analysis. |
| RESULTS | |
| LC50 | > 100 mg/L at 48 hours |
| NOEC (or LOEC) | 100 mg/L at 48 hours |
| Remarks - Results | There were no immobilised daphnids in the range finding test (single sample of 10 daphnids) or the definitive test (quadruplicate samples of 5 daphnids). Sensitivity to the positive control (potassium dichromate) was within the normal range. |
| CONCLUSION | Not harmful to daphnids. |
| TEST FACILITY | SafePharm Laboratories (2007l) |

### C.2.3. Algal growth inhibition test

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 201 Alga, Growth Inhibition Test.<br>EC Directive 92/69/EEC C.3 Algal Inhibition Test. |
| Species | *Desmodesmus subspicatus* |
| Exposure Period | 72 hours |
| Concentration Range | The range finding test used concentrations of 0.1, 1, 10 and 100 mg/L. The definitive test was conducted at a single limit concentration of 100 mg/L. All concentrations were confirmed by analysis. |
| Auxiliary Solvent | None |
| Water Hardness | Not reported |
| Analytical Monitoring | HPLC |
| Remarks - Method | The test was modified by increasing the light intensity and decreasing the sample volume, because the test substance absorbs at 665 nm. Cell densities in controls increased by a factor of 79, satisfying the guideline requirement for a 16-fold increase. |
| RESULTS | |
| Remarks - Results | There were no effects on growth rate, yield and biomass of the algal culture after 72 hours exposure to 100 mg/L. Sensitivity to the positive control (potassium dichromate) was within the normal range. |
| CONCLUSION | Not harmful to green algae. |
| TEST FACILITY | SafePharm Laboratories (2007m) |

### C.2.4. Inhibition of microbial activity

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 209 Activated Sludge, Respiration Inhibition Test. |

| | |
|---|---|
| Inoculum | A mixed population of activated sewage sludge micro-organisms was obtained for the range-finding test and for the definitive test from the aeration stage of the Severn Trent Water Plc sewage treatment plant at UK which treats predominantly domestic sewage. |
| Exposure Period | 3 hours |
| Concentration Range | Nominal: 1000 mg/L |
| Remarks – Method | A range finding test was conducted by incubating sewage sludge in the presence of 100 and 1,000 mg/L of the notified chemical. On the basis of the range finding test a limit test was conducted by incubating triplicate samples of sewage sludge with 1,000 mg/L of the notified chemical. Reference substance concentrations of 3.2 and 32 mg/L were used. |
| RESULTS | |
| IC50 | > 1000 mg/L |
| NOEC | 1000 mg/L |
| Remarks – Results | The IC50 of 3,5-dichlorophenol was 9.5 mg/L. Observations made throughout the test period showed that all test vessels contained a very dark blue dispersion with no undissolved test substance visible. |
| CONCLUSION | The notified chemical is practically non-inhibitory to sewage sludge microorganisms. |
| TEST FACILITY | SafePharm Laboratories (2008d) |

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