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July 2009

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

# FULL PUBLIC REPORT

## Magenta T-43

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

## Magenta T-43

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Oce-Australia Ltd
2 International Court
Caribbean Gardens
Scoresby VIC 3179

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, Other names, CAS No, Molecular formula, Structural formula, Molecular weight, Spectral data, Method of detection and determination, Degree of purity, Identity of non-hazardous impurities, Import volume, Details of use, and Identity of recipients.

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)
Nil

NOTIFICATION IN OTHER COUNTRIES
UK, 2008

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
JPD Magenta T-43, MKDM-120, MKDM-130

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC,, GPC, UV/Vis, Mass spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY >85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

| | | | |
|---|---|---|---|
| *Chemical Name* | Polysodium salt of an azo linked heterocyclic aromatic system | | |
| *CAS No.* | Not assigned | *Weight %* | <2 |

| | | | |
|---|---|---|---|
| *Chemical Name* | Sodium chloride | | |
| *CAS No.* | 7647-14-5 | *Weight %* | <0.5 |

| | | | |
|---|---|---|---|
| *Chemical Name* | Water | | |
| *CAS No.* | 7732-18-5 | *Weight %* | <8 |
| *Chemical Name* | 7 unidentified impurities | | |
| *CAS No.* | Not assigned | *Weight %* | <5 |

ADDITIVES/ADJUVANTS None

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Dark red solid

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | >360°C | Measured |
| Boiling Point | --- | Not determined as the melting point was >360°C |
| Density | 1.77 x $10^3$ kg/$m^3$ at 22°C | Measured |
| Vapour Pressure | 6.2 x $10^{-5}$ kPa at 25°C | Measured |
| Water Solubility | 30.0 to 31.9% w/w of solution at 20°C by visual assessment | Measured |
| Hydrolysis as a Function of pH | Stable (half-lives > 1 year at pH 5, 7 and 9) | Measured |
| Partition Coefficient (n-octanol/water) | log $P_{ow}$ < -4.01 at 25°C | Measured |
| Adsorption/Desorption | log $K_{oc}$ < 1.25 at 30°C | Measured |
| Dissociation Constant | pKa = 3.14, 3.64, 4.61, 10.96 | Estimated |
| Particle Size | Inhalable fraction (<100 μm): 60.5%<br>Respirable fraction (<10 μm): 1.98% | Measured |
| Flash Point | --- | Not applicable for solid |
| Solid flammability | Not highly flammable | Measured |
| Autoignition Temperature | 362°C | Measured |
| Explosive Properties | Not explosive | Measured |
| Oxidizing Properties | Non-oxidising | Measured |

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

*Reactivity*
The notified chemical is stable under normal working conditions and has no known reactions with water or air.

*Dangerous Goods classification*
Based on the available data, the notified chemical is not classified as a Dangerous Goods according to the Australian Dangerous Goods Code (NTC, 2007).

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia and will be shipped from overseas in sealed inkjet printer 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
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be shipped into Australia in sealed industrial inkjet printer cartridges, packaged in a 20 L plastic container and housed within a 20 L cardboard box. The cartridges are distributed to the printing companies and are stored until time of use.

USE
The notified chemical will be used as a component (<10%) of industrial inkjet printer cartridges.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of industrial inkjet printer cartridges and there will not be any processing or reformulation in Australia. The cartridges will be supplied exclusively to industry for use with specialised inkjet printing machines and the typical substrate used for printing will be paper.

When changing ink containers, the transfer tube will be removed from the spent ink container and replaced with a new ink container. The transfer tube will then be replaced inside the new ink container and the printing machine will begin to draw in the ink. When the inkjet container is empty, it is disconnected from the industrial inkjet printer and disposed off via a suitable means.

The cartridges will be printed onto paper or other types of material by the industrial inkjet printer, mainly in a closed process. Once the cartridges ink is dried, the notified chemical will not be available for exposure and the printed products will be distributed to the general public.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| *Category of Worker* | *Number* | *Exposure Duration (hours/day)* | *Exposure Frequency (days/year)* |
|---|---|---|---|
| Printing machine operators (change of ink container) | 1-3 | <10 seconds | 2-3 times/month |
| Service and maintenance engineers | <10 | 1h/day | 2-3 times/month |

EXPOSURE DETAILS
There is potential for dermal and ocular exposure to ink containing the notified chemical during end use in industrial printing applications. However, under normal use conditions, the only exposure would be to printing machine operators when replacing ink cartridges and during printing process.

Printing machine operators may have dermal or ocular contact with the ink containing (<10%) notified chemical during replacing ink cartridges. However, exposure is expected to be low and for a brief period of time. Furthermore, printing machine operators are expected to wear personal protective equipment (PPE), such as gloves, goggles, and overalls to reduce exposure to the notified chemical during replacement of ink cartridge.

Dermal and ocular exposure is also expected to be minimal during printing process as printing is carried out within a closed and automated system. Inhalation exposure to the ink containing (<10%) notified chemical is also expected to be minimal, as printing is a closed process and aerosols are not expected to be generated during the printing process.

Service and maintenance engineers may have dermal or ocular exposure to the notified chemical when printing

machines require servicing/maintenance or repair. It is unlikely that engineers would be exposed to the wet ink, however any exposure of this type would be low and for a brief period of time. It is expected that engineers would wear appropriate PPE such as gloves, goggles with side splash protection and full cover overalls, to reduce exposure to the notified chemical.

Exposure is unlikely during transport and storage due to the nature of packaging.

### 6.1.2. Public exposure

The inkjet printer cartridges containing the notified chemical are only for industrial use situations and will not be sold to the public. Therefore, public will not be exposed to the notified chemical or ink containing it. However, the public will be exposed to the paper or other types of material printed with cartridge ink containing the notified chemical. Exposure to the general public, in this case, will be low as the notified chemical will be bound to the paper or other print substrate once the ink has dried and is not expected to be bioavailable.

## 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<br>low toxicity |
| Rabbit, skin irritation | non-irritating |
| Rabbit, eye irritation | irritating |
| Mouse, skin sensitisation – Local lymph node assay | evidence of sensitisation |
| Mutagenicity – bacterial reverse mutation | non mutagenic |

Toxicokinetics, metabolism and distribution.
No data was available to assess toxicokinetics, metabolism and distribution of the notified chemical. Dermal absorption is expected to be limited by the large molecular weight and low Kow of the notified chemical.

Acute toxicity.
The notified chemical was of low acute oral toxicity in rats. Acute dermal toxicity and acute inhalation toxicity studies were not conducted.

Irritation and Sensitisation.
The notified chemical was not irritating to the skin of rabbits, but was irritating to the eyes of rabbits in acute studies. The notified chemical was a sensitiser in mouse local lymph node assay (LLNA).

Repeated Dose Toxicity (sub acute, sub chronic, chronic).
No data was available to assess the potential for repeat dose toxicity.

Mutagenicity.
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test. Other mutagenicity tests were not conducted on the notified chemical and as such, it is not possible to fully evaluate the mutgaenicity potentials of the notified chemical. However, based on bacterial reverse mutation test, the notified chemical is not expected to be genotoxic.

Azo dyes are a concern for their potential induction of mutagenicity and carcinogenicity. The azo linkage is the most labile portion of an azo dye molecule, and it is readily enzymatically metabolised in mammals, including man (SCCNFP, 2002). Liver azo reductase enzymes reductively cleave the molecule into component amines. Some metabolism may also occur in the cells of the bladder wall, and during percutaneous absorption. Anaerobic intestinal bacteria are also capable of reductive cleavage of the azo linkage.

The aromatic amines that arise from the azo reduction of azo dyes are thought to be activated through their *N*-oxidation by cytochrome P450 isozymes (SCCNFP, 2002). These *N*-hydroxylarylamines may be further glucuronated (activated) or acetylated (inactivated), which may influence their mutagenicity (Bartsch, 1981). Under acidic pH, they form reactive nitrenium ions that can alkylate bases in DNA, particularly the nucleophilic centres in guanine. This mechanism is thought to contribute to the carcinogenicity of many azo dyes.

The notified chemical is not expected to be reductively cleaved to release any of the restricted aromatic amines specified in either the Appendix to EC Directive 76/769/EEC (EC, 2004) or the annexes of EU SCCNFP/0495/01 (SCCNFP, 2002). However, the notified chemical can be broken by azo reduction into a number of arylamine species, although these are unlikely to be mutagenic.

In addition, azo dyes are renowned for their content of impurities, particularly for the presence of component arylamines (SCCNFP, 2002; Øllgaard *et al* 1998). Such impurities are thought to contribute to their carcinogenicity, as these species may be more readily absorbed, and activated as carcinogens. The HPLC trace provided by the notifier indicates that the sample of the notified chemical contains a number of impurities. The impurities have been identified to be isomers of the notified chemical. As such, the impurities are unlikely to contribute to carcinogenicity of the notified chemical.

Carcinogenicity.
No data was available to assess the potential for carcinogenicity.

Toxicity for reproduction.
No data was available to assess the potential for toxicity for reproduction.

***Health hazard classification***
Based on the sensitising effect, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with a risk phrase R43: May cause sensitisation by skin contact

Although the notified chemical is an eye irritant in rabbits, the test scores does not warrant classification for an eye irritation.

### 6.3. Human health risk characterisation

#### 6.3.1. Occupational health and safety
The notified chemical was of low acute oral toxicity in rats. Acute dermal toxicity and acute inhalation toxicity studies were not conducted. The notified chemical was not irritating to the skin of rabbits, but was irritating to the eyes of rabbits in acute studies. The notified chemical was a sensitiser in mouse local lymph node assay (LLNA). The notified chemical is not expected to be genotoxic. Therefore, the main acute risk from the use of notified chemical is eye irritation and skin sensitisation. However, as the notified chemical will be present at <10% in the imported cartridges, acute risk of eye irritation is not warranted.

There is a risk for potential occupational exposure to the notified chemical during end use industrial printing applications, such as replacing ink cartridges and printing. However, occupational exposure is expected to be low and for a brief period of time during replacement of ink cartridges and printing will be carried out within a closed and automated system. Furthermore, printing machine operators are expected to wear PPE, such as gloves, goggles, and overalls during replacement of ink cartridge. Therefore, considering the exposure level and the use of PPE, the risk of occupational exposure is expected to be low and considered acceptable during replacement of ink cartridges and printing.

Service and maintenance engineers may also be at risk of occupational exposure to the notified chemical when printing machines require servicing/maintenance or repair. However, any exposure of this type would be low and for a brief period of time and it is expected that engineers would wear appropriate PPE such as gloves, goggles with side splash protection and full cover overalls, to reduce exposure to the notified chemical. Therefore, the risk is negligible and considered acceptable.

During transport and storage, the risk of worker exposure is minimal and acceptable as workers will only be exposed to the notified chemical in the case of an accident involving damage to the packaging and to wrapping.

### 6.3.2. Public health

The inkjet printer cartridges containing the notified chemical are only for industrial use situations and will not be sold to public. Therefore, public will not be exposed to the notified chemical or ink containing it as such. However, public will be exposed to the paper or other types of material printed with cartridge ink containing the notified chemical. In this case, the exposure will be minimal as the notified chemical will be bound to the paper or other print substrates once the ink has dried.

Therefore, the risk is not considered unacceptable, given that exposure is expected to be very low.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Environmental Exposure & Fate Assessment

#### 7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Environmental exposure to the notified chemical is very unlikely during transport and storage as it is manufactured overseas and imported in sealed cartridges.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be bound to paper as part of an inert matrix when it is used as proposed in industrial printing. Any spills would be contained with absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The inkjet cartridges are expected to be disposed of to landfill when they are empty. Waste paper may be recycled, incinerated or disposed of to landfill. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped 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.

#### 7.1.2 Environmental fate

The notified chemical is water soluble and not readily biodegradable, and could therefore be expected to pass through recycling processes and sewage treatment works without substantial removal through sorption and degradation. However, some removal may be expected with sludge as insoluble calcium salts, for example. Residues entering aquatic environments are expected to disperse and slowly degrade, with bioaccumulation precluded by the high molecular weight and water solubility.

When waste paper is disposed of to landfill, the notified chemical is expected to remain attached to the fibres and to slowly degrade. Incineration would destroy the notified chemical.

### 7.1.3 Predicted Environmental Concentration (PEC)

The PECs can be determined based on the assumption of 50% release from paper recycling via sewage treatment works to receiving waters, as outlined below.

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 1000 | 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 | 365 | days/year |
| Daily chemical release: | 1.37 | 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: | 0.32 | µg/L |
| PEC - Ocean: | 0.032 | 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* |
|---|---|---|
| Daphnia Toxicity | EC50 = 61 mg/L | Harmful |

### 7.2.1 Predicted No-Effect Concentration (PNEC)

The PNEC can be calculated by applicxation of a thousand fold assessment factor to the only available acute endpoint for the aquatic environment, as outlined below.

| Predicted No-Effect Concentration for the Aquatic Compartment | | |
|---|---|---|
| Acute toxicity to daphnids | 61 | mg/L |
| Assessment Factor | 1000 | |
| PNEC: | 61 | µg/L |

### 7.3. Environmental risk assessment

The risk quotients (PEC/PNEC) are tabulated below.

| Risk Assessment | PEC µg/L | PNEC µg/L | Q |
|---|---|---|---|
| Q - River | 0.32 | 61 | **0.005** |
| Q - Ocean | 0.032 | 61 | **0.0005** |

The PEC/PNEC ratios in the natural aquatic environment are much less than 1, indicating low risk for aquatic organisms.

## 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)]. The classification and labelling details are:

R43: May cause sensitisation by skin contact

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* |
|---|---|---|
| Skin Sensitisation | 1 | May cause an allergic skin reaction |
| | Acute 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 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

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact

- Use the following risk phrase for products/mixtures containing the notified chemical:
  - ≥1%: R43 May cause sensitisation by skin contact

Health Surveillance

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

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 introduced in the product MKDM-130:
  - Avoid contact with the skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product MKDM-130:
  - Gloves, protective clothing

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

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

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

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by 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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from as a component of industrial inkjet printer cartridges, 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 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

Physico-chemical properties were conducted on a commercial grade of the notified chemical containing >85% of notified chemical.

**Melting Point/Freezing Point** >360°C

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

**Density** $1.77 \times 10^3$ kg/m$^3$ at 22°C

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 Ltd (2007a)

**Vapour Pressure** $6.2 \times 10^{-5}$ kPa at 25°C

Method OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance.
Test Facility SafePharm Laboratories Ltd (2007b)

**Water Solubility** 30.0 to 31.9% w/w of solution at 20°C by visual assessment

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Standard methods were not applicable due to the high water solubility of the test material, which precluded preparation of samples at five times saturation level as specified in the guidelines. A number of individual samples were prepared at increasing nominal concentrations, with the solubility determined by visual assessment of the resulting solutions. At 31.9%, the red solution was underlain by a red gel containing excess test material.
Test Facility SafePharm Laboratories Ltd (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 120 hours* |
|---|---|---|
| 4 | 50 | 100% |
| 7 | 50 | 100% |
| 9 | 50 | 99.6% |

Remarks Sample solutions were prepared at a nominal 0.2 g/L. As there was less than 10% hydrolysis after 120 hours at 50°C, the half-life is > 1 year at 25°C.
Test Facility SafePharm Laboratories Ltd (2007c)

**Partition Coefficient (n-octanol/water)** log Pow < -4.01 at 22.5°C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Flask Method. The solubility of the notified chemical in *n*-octanol was < 6 mg/L.
Test Facility SafePharm Laboratories Ltd (2007a)

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

Method OECD TG 121 Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge Using HPLC.
Remarks The test was conducted at approximately neutral pH. The notified chemical eluted from the column before the reference substance acetanilide.
Test Facility SafePharm Laboratories Ltd (2007a)

**Dissociation Constant** pKa = 3.14, 3.64, 4.61, 10.96

Method Computer based estimation (ACD/pKa 8.03).
Remarks Attempts to measure the dissociation constants found no evidence of titration plateaus. The estimated values should be treated with caution as they are likely to be significantly affected by conjugation within the molecule.
Test Facility SafePharm Laboratories Ltd (2007a)

**Particle Size**

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

| *Range (μm)* | *Method* | *Result* |
|---|---|---|
| Proportion of test material having an inhalable particle size less than 100 μm | Sieve | 60.5% |
| Proportion of test material having a thoracic particle size less than 10 μm | Cascade Impactor | 1.77% |
| Proportion of test material having a respirable particle size less than 5.5 μm | Cascade Impactor | 0.210% |

Remarks Screening test (sieve method) and definitive test (cascade impactor method) were used.
Test Facility SafePharm Laboratories Ltd (2007a)

**Solid flammability** Not highly flammable as it failed to ignite in the preliminary screening test.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks
Test Facility SafePharm Laboratories Ltd (2007b)

**Autoignition Temperature** 362ºC

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test material was heated in an oven and the relative self ignition temperature determined.
Test Facility SafePharm Laboratories Ltd (2007b)

**Explosive Properties** Determined not to have explosive properties.

Method EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The test material was subjected to BAM fall hammer test, BAM friction test, and Koenen steel tube test for the determination of explosive properties.
Test Facility SafePharm Laboratories Ltd (2007b)

**Oxidizing Properties** Non-oxidising

Method EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks The structure of the test material was assessed for chemical groups that would imply oxidising properties.
Test Facility SafePharm Laboratories Ltd (2007b)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Toxicological investigations were conducted on a commercial grade of the notified chemical containing >85% of notified chemical.

### B.1. Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 420 Acute Oral Toxicity – Fixed Dose Method.<br>EC Directive 92/69/EEC B.1 Acute Toxicity (Oral). |
| Species/Strain | Rat/Sprague-Dawley CD |
| Vehicle | Distilled water |
| Remarks - Method | No significant protocol deviations. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 1 (F) | 2000 | 0 |
| 2 | 4 (F) | 2000 | 0 |

| | |
|---|---|
| LD50 | >2000 mg/kg bw |
| Signs of Toxicity | No signs of systemic toxicity were noted and there were no deaths. Red stained urine was noted in all animals during the day of dosing and one day dosing. |
| Effects in Organs | No abnormalities were noted at necropsy. |
| Remarks - Results | All animals showed expected gains in bodyweight over the study period. |
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |
| TEST FACILITY | SafePharm Laboratories Ltd (2007d) |

### B.2. Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical |
| METHOD | OECD TG 404 Acute Dermal Irritation/Corrosion.<br>EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation). |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | Test material was moistened with distilled water |
| Observation Period | 72 hours |
| Type of Dressing | Semi-occlusive. |
| Remarks - Method | No significant protocol deviations. |

RESULTS

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

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

| | |
|---|---|
| Remarks - Results | No evidence of skin irritation was noted during the study. Pink coloured staining was noted at all treated skin sites throughout the study. This did not effect evaluation of skin reactions. |
| CONCLUSION | The notified chemical is non-irritating to the skin. |

TEST FACILITY SafePharm Laboratories Ltd (2007e)

### B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Observation Period | 7 days |
| Remarks - Method | Due to a technical error, observations were performed on animal 1 on Day 5 and this score was used for 72 hours reading. |

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* | 1.67 | 0.67 | 0.67 | 2 | Day 5 | 0 |
| *Conjunctiva: chemosis* | 1.33 | 0.67 | 0.67 | 2 | Day 5 | 0 |
| *Conjunctiva: discharge* | 1.0 | 0.33 | 0.33 | 2 | 48 hours | 0 |
| *Corneal opacity* | 1.0 | 0.33 | 0.33 | 1 | Day 5 | 0 |
| *Iridial inflammation* | 0.33 | 0 | 0 | 1 | 24 hours | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**The effect was absent on Day 7 with respect to redness, chemosis, and opacity; on Day 5 with respect to discharge, and at 48 hours with respect to iridial inflammation.

| | |
|---|---|
| Remarks - Results | Red-coloured staining of the fur was noted around all treated eyes throughout the study. Staining of the cornea occurred, but was absent by Day 7.<br>Two treated eyes appeared normal at the 72-hour observation and the remaining treated eye appeared normal at the 7-day observation. |

CONCLUSION The notified chemical is irritating to the eye.

TEST FACILITY SafePharm Laboratories Ltd (2007f)

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

TEST SUBSTANCE Notified chemical

METHOD OECD Guidelines for the Testing of Chemicals No. 429 "Skin Sensitisation: Local Lymph Node Assay' (adopted 24 April 2002).
Method B42 Skin Sensitisation (Local Lymph Node Assay) of Commission Directive 2004/73/EC.

| | |
|---|---|
| Species/Strain | Mouse/CBA/Ca (CBA/CaBkl) |
| Vehicle | 1% pluronic L92 in distilled water |
| Remarks - Method | Following a preliminary test, three groups of four animals in each group, were treated with 50 µl (25 µl per ear) of the test material at the dose levels of 5%, 10% and 25% w/w.<br>2,4-Dinitrobenzenesulfonic acid, sodium salt as a solution in 1% pluronic L92 in distilled water at concentrations of 1%, 10% and 20% w/w, was the positive control used for the test in the laboratory. The stimulation index observed for the positive control were 1.39 (1%), 11.33 (10%), and 19.34 (20%). 2,4-Dinitrobenzenesulfonic acid, sodium salt was a sensitiser under the conditions of the test. |

RESULTS

| *Concentration (% w/w) in 1% pluronic L92 in distilled water* | *Proliferative response (DPM/lymph node)* | *Stimulation Index (Test/Control Ratio)* |
|---|---|---|
| Vehicle control | | |
| 0 | 496.99 | -- |
| Test Substance | | |
| 5% | 676.80 | 1.36 |
| 10% | 641.84 | 1.29 |
| 25% | 1597.72 | 3.21 |

Remarks - Results

There were no deaths. No signs of systemic toxicity were noted in the test or control animals during the test. Red-coloured staining on the ears was noted at all test sites post dose on Days 1 and 2 and for the remainder of the test.
A stimulation index of greater than three was recorded for the highest concentration of the test material. The test material was considered to be a sensitiser under the conditions of the test.

CONCLUSION

There was evidence of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY

SafePharm Laboratories Ltd (2007g)

**B.5. Genotoxicity – bacteria**

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain

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

Metabolic Activation System

Liver fraction (S9 mix) from rats pretreated with phenobarbital/5,6-benzoflavone

Concentration Range in Main Test

a) With metabolic activation: 0, 1.2, 4.9, 20, 78, 313, 1250, 5000 µg/plate
b) Without metabolic activation: 0, 1.2, 4.9, 20, 78, 313, 1250, 5000 µg/plate

Vehicle

Distilled water

Remarks - Method

No significant protocol deviations.

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 | >5000 | Negative |
| *Present* | | | | |
| Test 1 | >5000 | >5000 | >5000 | Negative |
| Test 2 | >5000 | >5000 | >5000 | Negative |

Remarks - Results

In the two main tests, neither an increase in the number of revertant colonies or a dose-related response was observed with or without metabolic activation.
No inhibition in the growth of the test strains was observed with or without metabolic activation.
No precipitate was observed on any of the concentration levels, with or without metabolic activation.
The revertant colonies of the positive controls showed an increase of

| | |
|---|---|
| | more than twice that of the negative controls and were within the control limit set in the background data, indicating that the study performed correctly. |
| CONCLUSION | The notified chemical was not mutagenic to bacteria under the conditions of the test. |
| TEST FACILITY | General Laboratory, BML (2007) |

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

These investigations were conducted on a commercial grade of the notified chemical containing >85% of notified chemical.

## 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 | Mixed sample of activated sewage sludge from various Japanese facilities. |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | BOD, TOC, HPLC |
| Remarks - Method | |

RESULTS

| *Test substance* | | *Aniline* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 7 | 1 | 7 | 59 |
| 14 | 1 | 14 | 74 |
| 21 | 1 | 21 | 79 |
| 28 | 1 | 28 | 79 |

| | |
|---|---|
| Remarks - Results | The notified chemical remained essentially unchanged during the test. |
| CONCLUSION | The notified chemical is not readily biodegradable. |
| TEST FACILITY | Kurume Laboratory (2007) |

### C.1.2. Bioaccumulation

The test was not conducted, as the notified chemical has high water solubility and a low partition coefficient, and is therefore not expected to bioconcentrate in fish.

## C.2. Ecotoxicological Investigations

### C.2.1. 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 | UV/VIS spectrophotometry |
| Remarks - Method | Nominal concentrations were confirmed by analysis |

RESULTS

| *Concentration mg/L* | | *Number of D. magna* | *Number Immobilised* | |
|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* |
| 0 | < LOQ | 20 | 0 | 0 |
| 10 | 10.4 | 20 | 0 | 0 |
| 18 | 18.9 | 20 | 0 | 0 |
| 32 | 33.7 | 20 | 0 | 0 |
| 56 | 59.2 | 20 | 0 | 7 |
| 100 | 104 | 20 | 0 | 100 |

| | |
|---|---|
| LC50 | > 100 mg/L at 24 hours<br>61 (54-69) mg/L at 48 hours (trimmed Spearman-Karber method) |
| NOEC | 32 mg/L at 48 hours |
| Remarks - Results | Sensitivity to potassium dichromate (48 hour EC50 = 0.79 mg/L) was in the normal range. |

CONCLUSION The notified chemical is harmful to daphnids.

TEST FACILITY SafePharm Laboratories Ltd (2008)

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