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

# FULL PUBLIC REPORT

## Magenta Dye 1

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**Director**

**Chemicals Notification and Assessment**

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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett-Packard Australia Pty Ltd (ABN 74004394763)
31 – 41 Joseph St
BLACKBURN VIC 3130

Toxikos Pty Ltd (ABN 30 095 051 791)
293 Waverly Road
MALVERN EAST VIC 3145

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 name, CAS No., molecular weight, molecular and structural formulae, manufacture/import volume, spectral data and composition.

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
USA, EU and Switzerland.

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Magenta Dye 1.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD: Infrared, ultraviolet/visible and nuclear magnetic resonance spectroscopy.

### 3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

ADDITIVES/ADJUVANTS
None.

## 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
In inkjet cartridges in cardboard boxes. The notified chemical is a component of magenta ink in a colour cartridge.

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

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

USE
As a dye for use in inkjet reprographic processes.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

PORT OF ENTRY
Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier or notifier's agent.

TRANSPORTATION AND PACKAGING
The inkjet cartridges will normally be packaged in small cardboard boxes packed in larger cardboard boxes.

### 5.2. Operation Description

The notified chemical is imported from overseas as a component of printer ink. The printer ink is contained in a sealed cartridge which itself is packaged in cardboard.

The cartridges will be transported and stored prior to national distribution where they will be used in office or home printing equipment. The cartridges will be installed/replaced either by office workers, service technicians or consumers.

### 5.3. Occupational exposure

*Number and Category of Workers*

| *Category of Worker* | *Number* | *Exposure Duration* | *Exposure Frequency* |
|---|---|---|---|
| Importation | 10 | 4 hr | 40 days/yr |
| Storage & Transport | 100 | 6 hr | 240 days/yr |
| Office worker / service technician / consumer | 10000 | <0.1 | 20 |

*Exposure Details*
Exposure to the notified chemical during the importation transport and storage of the printer cartridges is not expected except in the unlikely event of an accident where the sealed cartridge and its packaging may be breached.

Office workers and service technicians may be exposed to the notified chemical when changing printer cartridges with service technicians also potentially exposed during printer maintenance. However, the cartridges are designed to deposit ink on the paper with little remaining on the cartridge on in the printer itself.

Users of the printers may be exposed to the notified chemical during handling of printed paper,

particularly if the paper is handled before the ink is adequately dried or if printing to a non-absorbent substrate occurs by error. After the ink is dry the notified chemical is bound to the paper matrix and is not expected to be readily bioavailable.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported in sealed cartridges containing up to 90 g of formulated ink (with a maximum of 6% of the notified chemical). There will be no release to the environment due to reformulation or repackaging.

RELEASE OF CHEMICAL FROM USE

The ink cartridges 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 use. However, if leakage or spillage does occur, the quantity of ink released will be small and will be contained with absorbent material. These will presumably be disposed of to landfill in the normal office garbage along with the empty cartridges and print heads. The sealed cartridges are contained within the printer until they are removed for disposal. The disposal of uncured inks will be largely confined to residues contained in colour printing systems, which do not allow the replacement of individual colours. Environmental exposure will result from the disposal of printed-paper, discarded cartridges and any accidental leakage of the cartridges during use.

The notifier has not provided an estimate of the amount of residue in the spent cartridge, but expects up to 90 % of the notified substance will be bound to printed paper which will be disposed of to landfill, recycled or incinerated. Based on a maximum import volume of 1 tonne, up to 100 kg of the notified chemical will be sent to landfill as residue in empty toner cartridges.

The remaining 90% of the notified chemical (up to 900 kg) bound to paper which is expected to be recycled, disposed of to landfill or incinerated. If recycled, all of the developer containing the notified chemical will be removed from the paper/pulp during the deinking stage of the recycling process and the notified chemical will remain in the aquatic phase or end up in the resultant sludge, which will be disposed of to landfill.

## 5.5. Disposal

The total import volume of the notified chemical will ultimately be either disposed of to landfill or incinerated or recycled with paper.

## 5.6. Public exposure

Members of the public may be exposed to the notified chemical while changing cartridges or handling of the printed paper, particularly if the paper is handled before the ink is adequately dried or if printing to a non-absorbent substrate occurs by error. The notifier has calculated that each printed page contains 1.5 to 2 mg of dye. Once printed onto paper and dried, the notified chemical is bound and unavailable for release.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa** Dark red powder.

**Melting Point/Freezing Point** 309°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

**Boiling Point** > 400°C at 101.3 kPa

METHOD Theoretical assessment.

**Density** 1540 kg/$m^3$ at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.

**Vapour Pressure** << $10^{-3}$ Pa at 25°C (estimated).

METHOD The vapour pressure was estimated based on a theoretical assessment that recognised that within a homologous series of organic compounds, the boiling point rises and the vapour pressure at a given temperature falls with increasing molecular weight. A comparison made using a number of organic compounds showed that a compound with a molecular weight of the test substance would be expected to have a very high boiling point (e.g. > 400°C) and a correspondingly lower vapour pressure. By comparing the test substance with other compounds in the series examined, it was deduced that the vapour pressure at 25°C will be substantially less than $10^{-3}$ Pa.

**Water Solubility** 199 g/L at 25°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).
Remarks Approximately 5 g of the test substance and enough distilled water (to make the total weight 20, 20 and 15 g in test 1, 2 and 3, respectively) were put in three 25 mL centrifuge tubes and placed in a shaking water bath at 30°C ± 1 °C. After 24 hours further portions of test substance were added to each tube on an hourly basis to achieve a permanent saturation.

Test 1 was removed from the bath and allowed to equilibrate at 25°C ± 1 °C for 24 hours with occasional shaking, the contents then centrifuged for 30 minutes at 3000 rpm and allowed to re-equilibrate at 25°C ± 1 °C overnight. Tests 2 and 3 were treated similarly after initial equilibration at 30°C ± 1 °C for 48 and 72 hours, respectively.

After diluting (approximately 0.15-0.25 g of the aqueous test solution to 1 L with distilled water) the concentration of the test substance in the clear aqueous solution was determined using UV/Vis spectroscopy at 545 nm in a 1 cm cell. The mean of the three test results was 19.9% w/v (199 g/L).

The test substance is readily soluble in water (Mensink *et al.* 1995).

**Hydrolysis as a Function of pH**

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

| *pH* | *T (°C)* | *$t_{½}$ <hours or days>* |
|---|---|---|
| 4 | 50 | 792 hours |
| 7 | 50 | Not determined |
| 9 | 50 | Not determined |

Remarks Test solutions were analysed using HPLC. Hydrolysis in pH 7 and 9 buffers was less than 10% after 5 days therefore no further testing was conducted. At pH 4, hydrolysis was greater than 10% after 5 days at 50°C ± 0.5°C. Further testing showed that the $t_{½}$ was approximately 370 hours and 163 hours at 60°C and 70°C, respectively.

The test substance can be considered to be hydrolytically stable at pH 7 and 9 and slightly hydrolysing at pH 4 (Mensink *et al.* 1995).

**Partition Coefficient (n-octanol/water)** log Pow at 25°C = < -2.62

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Preliminary examination showed that the test substance readily dissolved in water and was fairly insoluble in n-octanol. A stock solution of approximately 0.0003 M in octanol pre-saturated water was prepared (Standard 1) and was diluted to ~ 0.00015 M (Standard 2) and ~ 0.00007 M (Standard 3). Test mixtures of octanol:water in the ratios of 1:1, 1:2 and 2:1 (v/v) were prepared from standards 1, 2 and 3, respectively. The test mixtures were shaken at 25°C ± 1°C for 2 hours and then centrifuged at 2000 rpm for 10 minutes, allowed to stand for at least 1 hour at 25°C ± 1°C. The two layers were sampled and the concentration of the test substance was determined using HPLC.

The low log $P_{ow}$ is consistent with the high water solubility indicating a low affinity for the organic phase and component of soils and sediments.

**Adsorption/Desorption** log $K_{oc}$ < 1.5

METHOD Draft OECD Guideline for the Testing of Chemicals (May 1997)
REMARKS Six reference substances with known log $K_{oc}$ values were used. The column dead time was determined using the inert substance sodium nitrate. All the substances were injected in duplicate onto the HPLC and were dissolved in the mobile phase, which consisted of 55% methanol and 45% phosphate buffer. The average retention times of 6 reference substances were determined.

However, the retention time of the test substance could not be determined as it was shorter than the column dead time. As validated by the test guideline it was concluded that the log $K_{oc}$ < 1.5

The low $K_{oc}$ value is consistent with the high water solubility of the test substance and indicates that the mobility of the notified chemical in soil as being very high (based on binding to organic matter in soil).

**Dissociation Constant** Not determined.

REMARKS As a salt of a very strong acid, the notified chemical should remain ionized throughout the environmental pH range of 4 to 9.

**Particle Size** 0.03% < 15 µm; 21% < 100 µm; 30% ≤ 115 µm.

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

| *Range (µm)* | *Mass (%)* |
|---|---|
| 0 - 15 | 0.03 |
| ≤ 100 | 21 |
| ≤ 115 | 30 |

**Surface Tension** 71.5 mN/m at 25°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension was measured as an approximately 0.1% w/v solution in

distilled water using a Krüss K12 tensiometer and the Wilhelmy plate method. No sonication was required due to the high water solubility of the test substance. Two tests were done by weighing 0.1057 and 0.0949 g of the test substance into 100 mL volumetric flasks up to the mark with distilled water and equilibrated at 25°C ± 1°C before measuring the surface tension (for 15 and 25 minutes for test 1 and 2, respectively).

The results indicate that the test substance is not surface active.

**Flash Point** Not applicable for a solid.

**Flammability Limits** Not flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.12 Flammability (Contact with Water).
EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids.

**Autoignition Temperature** 349°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test sample attained a temperature of 400°C by self-heating at an oven air temperature of 349°C.

**Explosive Properties** Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

**Oxidizing Properties** Not oxidizing.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).

**Reactivity**

Remarks Expected to be stable under normal environmental conditions; stable as solid at 54°C for 14 days.

## 7. TOXICOLOGICAL INVESTIGATIONS

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

### 7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 420 Acute Oral Toxicity – Fixed Dose Method.
EC Directive 92/69/EEC B.1bis Acute Oral Toxicity – Fixed Dose Method.
USEPA Health Effects Test Guidelines (1998), OPPTS 870.1200, Acute Oral Toxicity.

Species/Strain — Rat/Alpk:AP$_f$SD (Wistar derived)
Vehicle — Deionised water. Dose volume 10 mL/kg.

Remarks – Method — A preliminary study involved treatment of one animal per dose at 500 and 2000 mg/kg bw.

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5/sex | 2000 | 0/10 |

LD50 — > 2000 mg/kg bw
Signs of Toxicity — No clinical signs of toxicity.
Effects in Organs — Pelvic dilatation of the kidney in two males was considered to be spontaneous.
Remarks - Results — Pink staining of the fur was seen in all animals.

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

### 7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
USEPA Health Effects Test Guidelines (1998), OPPTS 870.1200, Acute Dermal Toxicity.

Species/Strain — Rat/Alpk:AP$_f$SD (Wistar derived)
Vehicle — Water.
Type of dressing — Occlusive.

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw* | *Mortality* |
|---|---|---|---|
| 1 | 5/sex | 2000 | 0/10 |

| | |
|---|---|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity - Local | Purple staining; scabs in two females. |
| Signs of Toxicity - Systemic | Weight loss by 2 animals/sex between days 1 and 8. |
| Effects in Organs | None. |
| Remarks - Results | Purple staining prevented full assessment of irritation. |

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

### 7.3. 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).<br>USEPA Health Effects Test Guidelines (1998), OPPTS 870.2500, Acute Dermal Irritation. |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | Water. |
| Observation Period | 3 days. |
| Type of Dressing | Occlusive. |
| Remarks - Method | As erythema could not be scored due to staining, histopathological examination was performed. |

RESULTS

| | |
|---|---|
| Remarks - Results | Minimal multifocal acanthosis and inflammatory cell infiltration was observed in 3 animals, hyperkeratosis in one of these and minimal parakeratosis in another. No oedema was observed in any animal at any time point. |

CONCLUSION The notified chemical is slightly irritating to skin.

### 7.4. Irritation - eye

TEST SUBSTANCE Notified chemical.

METHOD

| | |
|---|---|
| | OECD TG 405 Acute Eye Irritation/Corrosion.<br>EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).<br>USEPA Health Effects Test Guidelines (1998), OPPTS 870.2400, Acute Eye Irritation. |
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Observation Period | 7 days. |

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* | 0.67 | 1 | 0 | 1 | 3 days | 0 |
| *Conjunctiva: chemosis* | 0 | 0.33 | 0 | 1 | 1 day | 0 |
| *Conjunctiva: discharge* | 0.67 | 0 | 0 | 2 | 2 days | 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.

| | |
|---|---|
| Remarks - Results | Slight initial pain was reported on instillation. Pink staining prevented scoring of eyes at 1 hour but resolved by day 7. |
| CONCLUSION | The notified chemical is slightly irritating to the eye. |

### 7.6. Skin sensitisation

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical. |
| METHOD | OECD TG 406 Skin Sensitisation - maximisation.<br>EC Directive 96/54/EC B.6 Skin Sensitisation - maximisation. |
| Species/Strain | Guinea pig/Dunkin Hartley |
| PRELIMINARY STUDY | Maximum Non-irritating Concentration<br>intradermal: < 1% w/v<br>topical: 10 – 25% w/v |
| MAIN STUDY | |
| Number of Animals | Test Group: 10 Control Group: 5 |
| INDUCTION PHASE | Induction Concentration<br>intradermal injection: 1% w/v<br>topical application: 50% w/v |
| Signs of Irritation | Discrete or patchy slight erythema was observed at injection sites in a majority of control and test animals. |
| CHALLENGE PHASE | |
| 1st challenge | topical application: 10% w/v<br>topical application: 25% w/v |

RESULTS

| | |
|---|---|
| Remarks - Results | One of the control animals died during the study. No skin reactions were seen at challenge at either 24 or 48 hours after patch removal at 10% (w/v) or 25% (w/v). |
| CONCLUSION | There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. |

### 7.7. 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/Alpk:APfSD (Wistar derived) |
| Route of Administration | Oral – gavage. |
| Exposure Information | Total exposure days: 28 days;<br>Dose regimen: 7 days per week;<br>Post-exposure observation period: None. |
| Vehicle | Deionised water. |

RESULTS

| *Group* | *Number and Sex of Animals* | *Dose mg/kg bw/day* | *Mortality* |
|---|---|---|---|
| I (control) | 5/sex | 0 | None |
| II (low dose) | " | 15 | " |
| III (mid dose) | " | 150 | " |

| | | | |
|---|---|---|---|
| IV (high dose) | " | 1000 | " |

*Clinical Observations*
No treatment-related findings. At the high dose there was pink discolouration of internal and external tissues in all animals, a slightly decreased motor activity in high dose females and a trend to lower bodyweight in high dose females which achieved statistical significance on day 27.

*Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis*
*Clinical Chemistry* Plasma bilirubin appeared to be elevated in mid and high dose animals but this was attributed to colouring of the serum by the notified chemical. A number of changes in high dose animals were minimal and within the historical control values and were not considered to be of toxicological significance. These were high cholesterol in females, high total protein in both sexes, high triglycerides in males, low alkaline phosphatase, aspartate aminotransferase, potassium and phosphorus in females.

*Haematology* Some small changes in the low and mid dose groups were considered to have occurred by chance. No equivalent changes were seen in the high dose group.

*Effects in Organs*
*Organ weights* Adrenal weights relative to body weight were slightly higher in high dose males.

*Macroscopic findings* No significant findings apart from pink discolouration.

*Microscopic findings* Slight cortical tubular vacuolation in the kidney of high dose animals.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on slight kidney effects in high dose animals.

### 7.8. 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>ICH Harmonised Tripartite Guideline S2A. Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals, 1995, 1997.<br>Plate incorporation procedure/preincubation procedure |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98.<br>*E. coli*: WP2 uvrA (pKM101), WP2 (pKM101). |
| Metabolic Activation System | Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction. |
| Concentration Range in Main Test | a) With metabolic activation: 0 - 5000 µg/plate.<br>b) Without metabolic activation: 0 - 5000 µg/plate. |
| Vehicle | DMSO |
| Remarks – Method | 2 independent tests; the second study with metabolic activation used the pre-incubation procedure. |
| RESULTS | |
| Remarks - Results | No cytotoxicity or precipitation was observed. No significant increases in the numbers of revertant colonies either in the presence or absence of metabolic activation. Positive controls were used and in all cases resulted in large increases in revertants, confirming the sensitivity of the test system. |
| CONCLUSION | The notified chemical was not mutagenic to bacteria under the conditions of the test. |

### 7.9. Genotoxicity – in vitro

| | |
|---|---|
| TEST SUBSTANCE | Notified chemical. |
| METHOD | OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.<br>EC Directive 92/69/EEC – B10 In vitro Mammalian Cytogenetic Test. |
| Cell Type/Cell Line | Human peripheral blood lymphocytes. |
| Metabolic Activation System | Phenobarbital/β-naphthoflavone-induced rat liver S9 fraction. |
| Vehicle | Not stated. |

| *Metabolic Activation* | *Test Substance Concentration (µg/mL)* | *Exposure Period* | *Harvest Time* |
|---|---|---|---|
| *Absent* | | | |
| Test 1 | 10, 50, 100, 250, 500*, 2500*, 5000* | 3 hours | 20 hours |
| Test 2 | 10, 50, 100, 250, 500*, 1000*, 5000* | 20 hours | " |
| *Present* | | | |
| Test 1 | 10, 50, 100, 250, 500*, 2500*, 5000* | 3 hours | " |
| Test 2 | 10, 50, 100, 250, 500*, 2500*, 5000* | 3 hours | " |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/mL) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity* in PreliminaryTest* | *Cytotoxicity* in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | 5000 | 5000 | Not stated | None |
| Test 2 | 1000 | | " | " |
| *Present* | | | | |
| Test 1 | 2500 | 2500 | " | " |
| Test 2 | Nil | Nil | " | " |

*Reduction in mitotic index

| | |
|---|---|
| Remarks – Results | Positive controls were mitomycin C in the absence of metabolic activation and cyclophosphamide in its presence; these elevated the frequency of chromosomal aberrations significantly above control levels, thus demonstrating the sensitivity of the test. |
| CONCLUSION | The notified chemical was not clastogenic to human peripheral blood lymphocytes treated in vitro under the conditions of the test. |

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Magenta Dye 1 |
| METHOD | OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test. |
| Inoculum | Centrifuged, washed and resuspended activated sludge from a predominantly domestic sewage treatment works |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Chemical Oxygen Demand (COD) |
| Remarks - Method | In addition to the test substance, blank samples and samples containing a reference substance (sodium acetate) were measured. |

RESULTS

| *Test substance* | | *Sodium Acetate* | |
|---|---|---|---|
| *Day* | *% degradation* | *Day* | *% degradation* |
| 5 | <5 | 5 | 59 |
| 10 | <5 | 10 | 64 |
| 15 | <5 | 15 | 64 |
| 20 | <5 | 20 | 64 |
| 28 | <5 | 28 | 64 |

| | |
|---|---|
| Remarks - Results | Degradation of the reference substance indicates that the test system was valid. |
| CONCLUSION | The test substance is not readily biodegradable according to the OECD criteria requiring > 60% within 10 days of commencement. |

#### 8.1.2. Bioaccumulation

No bioaccumulation data were provided. However, if there is any release to the aquatic compartment bioaccumulation is not expected due to the high water solubility and the low log $P_{ow}$ of the notified chemical.

### 8.2. Ecotoxicological investigations

#### 8.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Magenta Dye 1 |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static |
| Species | Rainbow trout (*Oncorhynchus mykiss*) |
| Exposure Period | 96 hours |
| Auxiliary Solvent | None |
| Water Hardness | 45.7 mg $CaCO_3$/L |
| Analytical Monitoring | Spectrophotometric analysis |
| Remarks – Method | Samples were taken from the centre of the test solution for spectrophotometric analysis of concentration. Due to the intense colouration of the test solutions fish were netted into freshwater to assess mortality and no observations were made between 2 and 4 hours. Oxygen content, pH and temperature were all satisfactorily maintained. |

RESULTS

| *Concentration mg/L* | | *Number of Fish* | *Mortality* | | | |
|---|---|---|---|---|---|---|
| *Nominal* | *Actual* | | *24h* | *48h* | *72h* | *96h* |
| Dilution water control | - | 10 | 0 | 0 | 0 | 0 |
| 180 | 180 | 10 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LC50 | > 180 mg/L at 96 hours. |
| NOEC (or LOEC) | > 180 mg/L at 96 hours. |
| Remarks – Results | The mean measured concentration was 100% of the nominal concentration and the percentage loss in the measured concentration over the test period was < 1%. Symptoms of toxicity other than mortality could not be observed due to the intense colour of the test solutions. |
| CONCLUSION | The test substance is practically non-toxic to fish. |

### 8.2.2. Chronic toxicity to aquatic invertebrates

| | |
|---|---|
| TEST SUBSTANCE | Magenta Dye 1 |
| METHOD | OECD TG 202 Daphnia sp. Reproduction Test – Semi Static |
| Species | *Daphnia magna* |
| Exposure Period | 21 days |
| Auxiliary Solvent | None |
| Water Hardness | 218 (new) and 223 (old) mg $CaCO_3$/L in dilution water control. |
| Analytical Monitoring | Spectrophotometric analysis |
| Remarks - Method | Samples were taken from the centre of the new and old test solutions for spectrophotometric analysis of concentration. Oxygen content, pH and temperature were all satisfactorily maintained. It was not possible to determine hardness due to the intensity of colour in test solutions.<br><br>The mean measured concentrations in the new and old test solutions ranged from 94% to 100% and 95% to 100%, respectively therefore, the results are based on nominal concentrations of the test solutions. |

RESULTS

| *Concentration mg/L* | *Number of D. magna* | *% Mortality* | | | |
|---|---|---|---|---|---|
| *Nominal* | | *24 h* | *48 h* | *14 d* | *21 d* |
| Dilution water control | 10 | 0 | 0 | 0 | 0 |
| 5 | 10 | 0 | 0 | 0 | 0 |
| 10 | 10 | 0 | 0 | 0 | 10 |
| 20 | 10 | 0 | 0 | 0 | 10 |
| 40 | 10 | 0 | 0 | 0 | 20 |
| 80 | 10 | 0 | 0 | 0 | 100 |
| 160 | 10 | 0 | 0 | 100 | 100 |

| | |
|---|---|
| 21 day EC50<br>*(For reproduction)* | > 40 mg/L |

NOEC

| | |
|---|---|
| *Overall* | 20 mg/L at 21 days |
| *For length (of adults)* | 20 mg/L |
| *For reproduction* | 40 mg/L at 21 days |
| Remarks - Results | No dead offspring were observed in the study. Reproduction data were |

analysed using Bartlett's test and Student's T-test with Bonferroni's adjustment. Offspring produced by adults that died before Day 21 were excluded from statistical analysis.

CONCLUSION

The test substance is very slightly toxic to *Daphnia magna* adults (based on the 48 hour EC50 value estimated from the chronic study results) and very slightly toxic to daphnia based on the NOEC for reproduction (Mensink 1995).

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE: Magenta Dye 1

METHOD: OECD TG 201 Alga Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.

| | |
|---|---|
| Species | *Selenastrum capricornutum* |
| Exposure Period | 72 hours |
| Concentration Range Nominal | 1.0, 2.3, 5.0, 11, 25, 55 and 120 mg/L |
| Concentration Range Actual | 1.1, 2.5, 5.2, 11, 25, 57 and 120 mg/L |
| Auxiliary Solvent | None |
| Water Hardness | Standard test medium was used. |
| Analytical Monitoring | Spectrophotometric analysis |
| Remarks - Method | The test method was selected due to its suitability for coloured solutions enabling to determine whether the effects on algae is caused by the test substance or a reduction in light due to colour.<br><br>Four replicate cultures of the control and each test concentration were used with two replicates of the exposure and shaded test vessels for each test concentration. One blank (no algal medium) was incubated concurrently for each control and test concentration. |

RESULTS

| | *Growth - $E_rC50$* | *Biomass - $E_bC50$* | *NOEC* | *LOEC* |
|---|---|---|---|---|
| | *mg/L at 72 h* | *mg/L at 72 h* | *mg/L at 72 h* | *mg/L at 72 h* |
| Exposure solutions | 39 | 5.9 | 1 | 2.3 |
| Shaded solutions | 35 | 6.8 | 1 | 2.3 |

Remarks - Results: Due to the colouration of the test solutions, growth rate data were used in calculation of EC50 values and for all subsequent comparisons. Graphical comparisons of the percentages of inhibition in the exposure and shaded vessels were essentially the same. The graph plotted with the inhibition of growth rate in exposure vessels versus that in shaded vessels showed that the quotient of the inhibition of growth curves is higher than 0.9 for all test concentrations ($p = 0.05$).

CONCLUSION

The report indicates that the test substance satisfies the exemption clause in Annex VI (Dir.93/21/EEC) and the 72 hour EC50 for algae should not be used as a basis for classification.

### 8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Magenta Dye 1

| | |
|---|---|
| METHOD | OECD TG 209 Activated Sludge, Respiration Inhibition Test.<br>Ecological and Toxicological Association of Dyestuffs Manufacturers (ETAD) Method 103: Screening test for the assessment of the possible inhibitory effect of a test chemical on aerobic waste water bacteria. |
| Inoculum | Activated sludge obtained from a sewage treatment plant that treats sewage predominantly of domestic origin |
| Exposure Period | 3 hours |
| Concentration Range Nominal | 1.0, 3.2, 10, 32 and 100 mg/L |
| Remarks – Method | Test concentrations of the reference substance (3,5-dichlorophenol) were 1, 3.2, 10 and 30 mg/L. |
| RESULTS | |
| IC50 | > 100 mg/L |
| NOEC | 100 mg/L (highest concentration tested) |
| Remarks – Results | No significant effect on respiration was observed at any of the test concentrations used (% inhibition of the respiration rate < 10%). The IC50 of the reference substance was 9.6 mg/L, thus validating the test. |
| CONCLUSION | No microbial inhibition was observed at any of the test concentrations. |

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

The total import volume of the notified chemical will ultimately be either disposed of to landfill, incinerated or recycled with paper. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30 - 60% of the total amount of ink and therefore, at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. However, a greater proportion can be expected to remain in the aqueous phase due to the high water solubility of the notified chemical.

Recycling may take place in a number of centres throughout Australia. A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where the entire import volume (up to 1000 kg) is released to sewer during recycling and is not removed during sewage treatment processes (Environment Australia 2003). Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the daily release on a nationwide basis to receiving waters is estimated to be 2.74 kg/day, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.7 μg/L.

| | |
|---|---|
| Amount entering sewer annually | 20 kg |
| Population of Australia | 19.5 million |
| Amount of water used per person per day | 200 L |
| Number of days in a year | 365 |
| Estimated PEC | 0.703 μg/L |

Based on the respective dilution factors of 0 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.703 or 0.0703 μg/L, respectively.

**Fate**

The potential for bioaccumulation is low due to the low log $P_{ow}$ and the high water solubility, which is further reduced by the low levels of aquatic exposure. Although not readily biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified chemical due to abiotic or slow biotic processes. Incineration of waste paper and sludge will destroy the chemical with the generation of water vapour and oxides of carbon, nitrogen and sulphur as well as sodium salts.

#### 9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species was Daphnia with a 48 hour EC50 of > 160 mg/L (estimated from the chronic test).

| *Organism* | *Duration* | *End Point* | *mg/L* |
|---|---|---|---|
| Fish | 96-hr | LC50 | >180 |
| Daphnia | 48-hr | EC50 | >160 |

A predicted no effect concentration (PNEC - aquatic ecosystems) of > 0.16 mg/L (> 160 μg/L) has been derived by dividing the EC50 value by a worst-case scenario uncertainty (safety) factor of 1000 (as toxicity data are available only for two trophic levels).

#### 9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (to landfill or for recycling or incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the import volume, method of packaging and low concentration in ink (6%), release of the notified chemical to the environment is expected to be low and widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and any of the notified chemical partitioned to the supernatant water will be released to sewer.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is < 4.4 X $10^{-3}$ and < 4.4 X $10^{-4}$ for freshwater and marine water, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

### 9.2. Human health

#### 9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

There is low potential for worker exposure to the notified chemical when replacing spent cartridges as the ink formulations are in a liquid form and therefore are unlikely to generate residual dusts. Service technicians may occasionally experience skin contact with the notified chemical during maintenance, however, the notified chemical is at low concentrations (< 5%) in the ink formulations. Exposure to the notified chemical on printed paper is low as the dye is bound to the paper matrix although some dermal exposure may occur if the paper is handled prior to complete drying.

#### 9.2.2. Public health – exposure assessment

Public exposure through importation, transportation or storage is assessed as negligible. There is little potential for exposure during cartridge changes. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available except if the paper is handled prior to complete drying. Public exposure is assessed as low.

#### 9.2.3. Human health - effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats, was a slight skin and eye irritant, was not a skin sensitiser in guinea pigs and was neither mutagenic in bacteria nor clastogenic in human peripheral blood lymphocytes. In a 28-day study, rats were administered the notified chemical by oral gavage and the NOAEL was 150 mg/kg/day based on slight kidney effects. The notified chemical is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

#### 9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low given that the notified chemical is contained in enclosed cartridges and is not classified as hazardous.

#### 9.2.5. Public health – risk characterisation

Members of the public are not likely to make contact with the notified chemical during cartridge changes unless the cartridge is ruptured or otherwise tampered with. Additionally the notified chemical is present at low concentrations and is not classified as hazardous. Ink containing the notified chemical on the printed pages is bound to the paper and is not bioavailable.

Therefore, the risk to public health from exposure to the notified chemical is considered to be low.

## 10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

### 10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

For the environment it is not possible to categorise the notified chemical according to the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals.

### 10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern.

### 10.3. Human health risk assessment

#### 10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

#### 10.3.2. Public health

There is Negligible Concern to public health when used as indicated.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS for the ink containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### 11.2. Label

The label for the ink containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

## 12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of to either landfill or be incinerated or recycled with paper in accordance with local, state or national legislation.

Emergency procedures

- Spills/release of the notified chemical should be handled by containing, adsorbing and clearing up spillage and transferring to a container for disposal. Wash the spillage area clean.
- Do not allow spilled/released chemical or washings to enter drains, sewers or watercourses.

### 12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

## 13. BIBLIOGRAPHY


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