File No: LTD/1139

20 July 2005

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

# FULL PUBLIC REPORT

## M-1114

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is 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:

| | |
|---|---|
| Street Address: | 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA. |
| Postal Address: | GPO Box 58, SYDNEY NSW 2001, AUSTRALIA. |
| TEL: | + 61 2 8577 8800 |
| FAX | + 61 2 8577 8888 |
| Website: | www.nicnas.gov.au |

**Director**
**NICNAS**

# TABLE OF CONTENTS

# FULL PUBLIC REPORT

## M-1114

### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ilford Imaging Asia Pacific Pty Ltd (ABN 69 004 283 701) of Unit 1, 10 Duerdin Street CLAYTON NORTH VIC 3149.

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 number, molecular and structural formula, molecular weight, spectral data, composition, import volume, and manufacturing process.

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)
Not stated.

NOTIFICATION IN OTHER COUNTRIES
France (2002),
US EPA (2002),
Environment Canada (2003),

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
M-1114

METHODS OF DETECTION AND DETERMINATION

| | |
|---|---|
| ANALYTICAL METHOD | IR, UV/Vis and NMR<br>IR, UV/VIS AND NMR spectra were provided |

### 3. COMPOSITION

DEGREE OF PURITY
HIGH

### 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported.

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

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

USE
A component in printing ink.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, transport and storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Ilford Imaging Asia Pacific Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical is to be imported in sealed inkjet cartridges at a level of <5%. The volume of ink in inkjet cartridges ranges from 2 to 55 mL ink, but typically 25 mL. Cartridges containing the notified chemical will be delivered to consumers by road transport.

### 5.2. Operation description

The notified chemical is not manufactured in Australia. No reformulation or repackaging of the product containing the notified chemical occurs in Australia. Service technicians and office workers will handle the sealed ink-jet cartridge when replacing spent cartridges in printers.

### 5.3. Occupational exposure

*Number and Category of Workers*

| *Category of Worker* | *Number* | *Exposure Duration* | *Exposure Frequency* |
|---|---|---|---|
| Delivery to wharf | 10 | 4 hour/day | 40 days/year |
| Distribution (storage & transport) | 100 | 6 hours/day | 240 days/year |
| Office worker/service technician | 10000 | <0.1 hour/day | 20 days/year |

*Exposure Details*

*Importation, storage, transport and distribution*
Waterside, warehouse and transport/distribution workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

*Office workers and service technicians*
It is expected that up to 1000 printer service technicians and several thousand office workers may be potentially exposed to the notified chemical. Such workers may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, repairing or maintaining printers. Pre-packed ink cartridges are sealed and exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

Maintenance workers may potentially come in contact with the notified chemical more often than office workers. Occupational exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Printer maintenance personnel usually wear cotton disposable gloves.

Office workers may potentially come in irregular contact with the notified chemical when replacing ink cartridges. Exposure to the ink is minimised by the use of replacement instructions as recommended by the manufacture.

A considerable number of office workers may be potentially exposed to the notified chemical by contact with paper printed with printing inks containing the notified chemical. The notifier estimates that each printed page may contain up to approximately 0.5 mg of the notified chemical per printed page. Contact with paper printed with printing inks containing the notified chemical is unlikely to result in dermal exposure, as the notified chemical will be bound to the structure of the paper.

## 5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. The sealed cartridges will be imported from overseas. Thus there will be no environmental exposure associated with this process in Australia.

RELEASE OF CHEMICAL FROM USE

The notified chemical as part of the formulation contained in the cartridges will be used in printers. The notified chemical can potentially be released to the environment during the disposal of the spent inkjet cartridges which are to be disposed of by landfill or incineration.

In the end use process it would be expected that the notified chemical would be bound to the paper which will be landfilled, burned or recycled. Where recycling does not occur the notified chemical will be disposed of in landfills where it is expected to remain bound to the treated paper. In the event of leaching the environmental effects are expected to be negligible due to the low bioaccumulation potential of the notified chemical. Empty cartridges will be disposed of with normal office waste and eventually sent to landfill.

## 5.5. Disposal

The notified chemical is expected to bind firmly to the paper substrate which would be sent to landfill, burned or recycled. When recycled, the ink will be either oxidized by bleaching or released in effluent to the paper mill wastewater treatment process.

## 5.6. Public exposure

The public may be exposed to the notified chemical in the event of an accident during transport involving extensive breakage of cartridges.

The ink containing the notified chemical is contained in the cartridge and the physical design of the cartridge prevents those handling the cartridge from accidentally touching the ink. The design also prevents leakage of ink. The loading and removal of a cartridge into or from its containment area in a printer can be readily accomplished without any contact with ink. Skin contact with the ink may occur if an attempt is made to insert or remove a damaged cartridge or to correct a paper-jam. The public could be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridges and maintaining printers.

The public may potentially come in irregular contact with the notified chemical during replacement of printer ink cartridges. Exposure to the ink is minimised by the use of ink cartridge replacement instructions as recommended by the manufacture.

Contact with paper printed with printing inks containing the notified chemical is unlikely to result in dermal exposure, as the ink containing the notified chemical will be bound to the structure of the paper. .

# 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20ºC and 101.3 kPa** Dark red powder

**Melting Point/Freezing Point** >360ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks Based on the preliminary assay using the Kofler hot bench, the approximate melting point of the notified chemical was determined to be >260ºC. In the main test using the electrothermal method, no melting point of the notified chemical was

observed at temperatures of >360ºC and >400ºC.

TEST FACILITY SEPC (2002a).

**Boiling Point** >350ºC

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks The test material did not melt at about 350°C and thus boiling point was not able to be determined.

TEST FACILITY SEPC (2002c).

**Density** 1106 kg/$m^3$ 20ºC

**Vapour Pressure** Not determined.

Remarks The notified chemical is a solid which is unlikely to have a significant vapour pressure based on its solid structure and salt form.

**Water Solubility** >200 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Aliquots of approximately 0.1 g of the notified chemical were dissolved in 0.1, 0.5, 1, 2, 10, 100 and 200 mL of water. After shaking for approximately 10 min to 2 h, a visual assessment of solubility was made. In addition, approximately 0.5 g of the notified chemical was dissolved in 1 mL of water. After shaking for 1.5 h, a visual assessment of solubility was made. Above the solubility of 200 g/L, a "pastry" was observed. On the basis of these preliminary results, the notified chemical was considered to be highly soluble in water.

TEST FACILITY CIT (2002a).

**Hydrolysis as a Function of pH** Not determined

Remarks While there is the potential for the notified chemical to hydrolyse, this is expected to occur only under extreme pH conditions.

**Partition Coefficient (n-octanol/water)** log Pow = <-2.3 at 20ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The maximum solubility of the notified chemical in n-octanol was performed by mixing approximately 0.1 g of the notified chemical in varying volumes of n-octanol for approximately 1 h at room temperature. The preliminary test indicated that the notified chemical was weakly soluble in n-octanol (<1 g/L). Based on the water and octanol solubilities of the notified chemical, the log $P_{ow}$ was estimated.

TEST FACILITY CIT (2002b).

**Adsorption/Desorption** log $K_{oc}$ = -0.176

METHOD EC (2003) Technical Guidance Document on risk Assessment, Part III, page 26, Table 4.

Remarks The calculation was based on the Technical Guidance Document and the results of the partition coefficient from above. The notified chemical is related to nonhydrophobic substance and is defined by the following equation:
Log $K_{oc}$ = 0.52 X log$K_{ow}$ + 1.02

**Dissociation Constant** Not determined

Remarks The notified chemical is likely to remain dissociated under normal environmental

conditions because of the presence of acidic groups.

| | |
|---|---|
| **Particle Size** | Not determined. |
| Remarks | The notified chemical will be imported in a liquid form. |
| **Flash Point** | Not determined for a solid. |
| **Flammability Limits** | Not classified as highly flammable. |
| METHOD | EC Directive 92/69/EEC A.10 Flammability (Solids). |
| Remarks | GLP & QA.<br>The test item reddened without ignition or propagation. |
| TEST FACILITY | SEPC (2002). |
| **Autoignition Temperature** | Not flammable. |
| **Explosive Properties** | Nor classified. |
| **Reactivity** | Stable under normal conditions, but is reactive with strong oxidising agents. |

## 7. TOXICOLOGICAL INVESTIGATIONS

| *Endpoint and Result* | *Assessment Conclusion* |
|---|---|
| Rat, acute oral | LD50 >2000 mg/kg bw, low toxicity |
| Rabbit, skin irritation | irritating |
| Rabbit, eye irritation | irritating |
| Guinea pig, skin sensitisation – adjuvant test | inconclusive |
| Guinea pig, skin sensitisation – mouse local lymph node assay | no evidence of sensitisation |
| Genotoxicity – bacterial reverse mutation | non mutagenic |

### 7.1. Acute toxicity – oral

| | |
|---|---|
| NOTIFIED CHEMICAL | M-1114 |
| METHOD | OECD TG 401 Acute Oral Toxicity – Limit Test.<br>EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test. |
| Species/Strain | Rat/Sprague-Dawley |
| Vehicle | Water |
| Remarks – Method | GLP & QA. |

RESULTS

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

| | |
|---|---|
| LD50 | >2000 mg/kg bw |
| Signs of Toxicity | Red colouration of the extremities (limbs, ears, nose and tail) was observed in all the animals within 4 hours. |
| Effects in Organs | None. |
| Remarks – Results | None. |
| CONCLUSION | The notified chemical is of low toxicity via the oral route. |

TEST FACILITY CIT (2002c).

### 7.2. Irritation – skin

NOTIFIED CHEMICAL M-1114

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 3 |
| Vehicle | Water |
| Observation Period | Up to 13 days. |
| Type of Dressing | Semi-occlusive. |
| Remarks – Method | GLP & QA. |

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* | 2 | 2 | 1.3 | 2 | 13 days | 1 |
| *Oedema* | 0 | 0 | 0 | - | - | 0 |

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

Remarks – Results

No oedema was observed in the study. Red to purple colouration of the skin, which could mask possible slight to well-defined erythema in this study, was noted in two animals up to day 10 and one animal up to day 13. When the colouration became pink, no cutaneous reactions were observed. In two animals, erythema/eschar formation equivalent to a mean value of 2 was calculated on the basis of the scores at 24, 48, and 72 hours for each animal.

The Primary Irritation Index (PII) is calculated as 0.74.

CONCLUSION The notified chemical is considered to be irritating to skin.

TEST FACILITY CIT (2002d).

### 7.3. Irritation – eye

NOTIFIED CHEMICAL M-1114

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 | 19 days |
| Remarks – Method | GLP & QA. |

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* | 2 | 2 | 2 | 2 | Day 18 | 0 |
| *Conjunctiva: chemosis* | 3 | 3 | 1.3 | 3 | Day 15 | 0 |
| *Conjunctiva: discharge* | 2 | 2 | 2 | 2 | Day 5 | 0 |
| *Corneal opacity* | 1.3 | 1.3 | 1.3 | 2 | Day 8 | 0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| *Iridial inflammation* | 2 | 2 | 2 | 2 | Day 5 | 0 |

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

Remarks – Results: In two animals, oedema of the conjunctivae (chemosis) with a mean score of 3 was calculated on the basis of the scores at 24, 48, and 72 hours for each animal. The scores of conjunctival redness and iris inflammation were masked by the red colouration of the notified chemical. Whitish purulent conjunctival discharge was observed in all animals.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY: CIT (2002e).

### 7.4. Skin sensitisation

NOTIFIED CHEMICAL: M-1114

METHOD: OECD TG 406 Skin Sensitisation – maximisation method.
- Species/Strain: Guinea pig/Hartley
- PRELIMINARY STUDY: Maximum Non-irritating Concentration: Scoring was masked by red colouration of the skin.
- MAIN STUDY
  - Number of Animals: Test Group: 10/sex; Control Group: 5/sex
  - INDUCTION PHASE: Induction Concentration: intradermal: 5% in saline; topical: 30% in saline
  - Signs of Irritation: Scoring was masked by red colouration of the skin.
  - CHALLENGE PHASE
    - 1st challenge: topical: 30% in saline
  - Remarks – Method: GLP & QA.

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after: 1st challenge* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Test Group* | 30% | 19/19 | 19/19 |
| *Control Group* | 30% | 10/10 | 10/10 |

Remarks - Results: One female animal was found dead on day 19. The death was investigated and was not due to the treatment.

Magenta colouration of the skin could have masked a possible marked erythema.

CONCLUSION: The notified chemical may have skin sensitising ability but the test conditions employed are inadequate or not sufficiently documented. Therefore, on the basis of inadequate evidence, no conclusion is made.

TEST FACILITY: CIT (2002f).

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

NOTIFIED CHEMICAL: M-1114

| | |
|---|---|
| METHOD | OECD TG 429 Skin Sensitisation: Local Lymph Node Assay. |
| Species/Strain | Mouse/CBA/J |
| Vehicle | 50% ethanol (w/w) |
| Remarks - Method | GLP & QA. Due to unsatisfactory solubility in acetone/olive oil or DMF, a mixture of ethanol/water (50/50 v/v) was chosen as the vehicle. Consequently, the concentration selected in the preliminary test were 5%, 2.5%, 1 and 0.5%. Since the notified chemical was non-irritant in the preliminary test, the highest dose-level retained for the main study was 5%. |

RESULTS

| *Concentration* | *Number of animal* | *Proliferative response (DPM/lymph node)* | *Stimulation Index (Test/Control Ratio)* |
|---|---|---|---|
| Notified chemical | | | |
| 1% | 4 | 62.20 | 1.39 |
| 2.5% | 4 | 86.61 | 1.94 |
| 5% | 4 | 32.27 | 0.72 |
| Vehicle Control | 4 | 44.73 | - |
| Positive Control* | 4 | 889.01 | 19.88 |

* 25% of α-hexylcinnamaldehyde was served as the positive control.

| | |
|---|---|
| Remarks - Results | There were no deaths or clinical signs during the study. A slight bodyweight loss was recorded in 3/4 animals in the 5% treatment group and the positive control groups.<br><br>Red colouration of the ears was noted in all notified chemical groups, but no increase of ear thickness was observed.<br><br>The Stimulation Index showed that the notified chemical is not a sensitiser. |
| CONCLUSION | There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test. |
| TEST FACILITY | CIT (2002g). |

### 7.6. Genotoxicity – bacteria

| | |
|---|---|
| NOTIFIED CHEMICAL | M-1114 |
| 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 & Pre incubation procedure |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.<br>*E. coli*: WP2 uvrA. |
| Metabolic Activation System | S9 mix |
| Concentration Range in Main Test | a) With metabolic activation: 0-5000 µg/plate.<br>b) Without metabolic activation: 0-5000 µg/plate. |
| Vehicle | Water |
| Remarks - Method | GLP & QA. All concentrations were expressed as active substance, taking account of the purity of the test material. No significant protocol deviations reported. |

RESULTS

| *Metabolic* | *Notified chemical Concentration (µg/plate) Resulting in:* |
|---|---|

| *Activation* | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
|---|---|---|---|---|
| *Absent* | 5000 | | >5000 | |
| Test 1 | | >5000 | >5000 | Not observed |
| Test 2 | | >5000 | >5000 | Not observed |
| *Present* | 5000 | | >5000 | |
| Test 1 | | >5000 | >5000 | Not observed |
| Test 2 | | >5000 | >5000 | Not observed |
| Test 3 | | >5000 | >5000 | Not observed |

Remarks - Results: Colouration of agar was observed in the study. No noteworthy toxicity was induced in the test strains in all experiments with and with out activation.

In TA 102 strain, more than two-fold increases in the number of revertants, without any evidence of dose-relationship, were noted in the first test. This increase was not confirmed in the repeated test. The number of revertants for the vehicle and positive controls was as expected. The study was therefore considered valid.

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

TEST FACILITY: CIT (2001).

### 7.7. Carcinogenesis Evaluation

The notifier provided a structure-activity relationship (SAR) analysis on the two reduction products of the notified chemical. The levels of carcinogenicity concern for the two reduction products were considered low.

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Ready biodegradability

NOTIFIED CHEMICAL: Notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: $CO_2$ Evolution (Modified Sturm Test).
EEC Directive 92/69 Method C4C (1992)

Inoculum: Activated sludge from sewage treatment plant
Exposure Period: 28 days
Auxiliary Solvent: None
Analytical Monitoring: Back titration of a titre of $Ba(OH)_2$ from the $CO_2$ traps with HCl.
Remarks - Method: The test consists of duplicates of control flasks, notified chemical flasks (15 mg TOC/L) and toxicity control flask. Sodium acetate (12.3 mg TOC/L) was used as the reference. Samples were collected on Days 2, 5, 7, 9, 12, 14, 16, 19, 23 and 28. On day 28 test vessels were treated with concentrated hydrochloric acid to drive off any inorganic carbonates formed. Temperatures and pH were within acceptable limits during the test.

RESULTS

| *Notified chemical* | | *Sodium acetate* | |
|---|---|---|---|
| *Day* | *% degradation* | *Day* | *% degradation* |
| 2 | 0 | 2 | 13 |
| 9 | 1 | 9 | 58 |

| | | | |
|---|---|---|---|
| 14 | 3 | 14 | 72 |
| 19 | 4 | 19 | 78 |
| 28 | 6 | 28 | 112* |

* It was assumed that the biodegradation was 100% after 28 days

| | |
|---|---|
| Remarks - Results | The notified chemical was degraded to 6% within 28 days. Due to the low biodegradation of the notified chemical, the difference of biodegradation between the notified chemical duplicates was higher than 20% at the end of the test. Biodegradation of the reference substance was 72% after 14 days thus confirming the validity of the test. The notified chemical was not toxic to the inoculum as the biodegradation of the toxicity control was higher than 25% in 14 days. |
| CONCLUSION | The notified chemical is considered not readily biodegradable. |
| TEST FACILITY | SEPC (2002d) |

### 8.1.2. Bioaccumulation

Based on the log Pow of <-2.3, the notified chemical is unlikely to bioaccumulate.

## 8.2. Ecotoxicological investigations

### 8.2.1. Acute toxicity to fish

| | |
|---|---|
| NOTIFIED CHEMICAL | Notified chemical |
| METHOD | OECD TG 203 Fish, Acute Toxicity Test – static conditions<br>EC Directive 92/69/EEC C.1 Acute Toxicity for Fish |
| Species | Rainbow trout (*Oncorhynchus mykiss*) |
| Exposure Period | 96 h |
| Auxiliary Solvent | None |
| Water Hardness | 150 ± 20 mg $CaCO_3$/L |
| Analytical Monitoring | HPLC |
| Remarks – Method | Based on the range-finding test, seven fish were used for treatment at a nominal concentration of 100 mg/L. Observations for mortality, and sub-lethal effects such as swimming at the surface of the solution, severe loss of equilibrium, hyperactive swimming behaviour, spasmodic swimming, animals lying at the bottom of the aquarium, colour change, abnormal respiratory rate were performed at 0, 2, 4, 24, 48 72 and 96 h. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test. |

RESULTS

| *Concentration mg/L* | *Number of Fish* | *Mortality* | | | | | |
|---|---|---|---|---|---|---|---|
| *Nominal* | | *2 h* | *4 h* | *24 h* | *48 h* | *72 h* | *96 h* |
| 100 | 7 | 0 | 0 | 0 | 0 | 0 | 0 |
| Control | 7 | 0 | 0 | 0 | 0 | 0 | 0 |

| | |
|---|---|
| LC50 | >100 mg/L at 96 h (nominal) |
| NOEC | 100 mg/L at 96 h (nominal) |
| Remarks – Results | No mortality or sub-lethal effects were observed at the limit concentration tested. The measured concentrations were within 20% of the nominal value throughout the test. |
| CONCLUSION | The notified chemical is considered to be practically non-toxic to fish. |
| TEST FACILITY | CIT (2004) |

### 8.2.2. Inhibition of microbial activity

NOTIFIED CHEMICAL

| | |
|---|---|
| METHOD | OECD TG 209 Activated Sludge, Respiration Inhibition Test.<br>EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test |
| Inoculum | Activated sludge collected from a domestic water treatment plant |
| Exposure Period | 3 h |
| Concentration Range Nominal | 10-1000 mg/L |
| Remarks – Method | The test consists of two controls, five treatments at nominal concentrations of 10, 31.6, 100, 316 and 1000 mg/L and 3,5-dichlorophenol as reference at nominal concentrations of 4, 12 and 36 mg/L. After 3 h incubation period the concentrations of dissolved oxygen were measured. |
| RESULTS | |
| IC50 | >1000 mg/L (nominal) |
| NOEC | 1000 mg/L (nominal) |
| Remarks – Results | As the difference between the two controls was below 15% and the 3 h EC50 of 11.1 mg/L for the reference was between 5 and 30 mg/L, the test was considered valid. |
| CONCLUSION | The notified chemical is not inhibitory to the activated sludge micro-organisms. |
| TEST FACILITY | CIT (2002h) |

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

Most of the notified chemical will be bound to paper, with the fate of the notified chemical dictated by paper disposal trends. The three main routes of paper disposal are landfill, incineration and recycling. Recent literature suggests that current paper recycling rates in Australia are 70-92% (Australian Environmental Review, 2001). Consequently, most of the paper containing the notified polymer could be recycled.

Paper recycling is carried out in paper mills, where it is likely that at least primary sedimentation occurs, and with some facilities also having biological treatment facilities. Therefore, in these facilities it is expected the notified chemical to partially partition into sludge under the usual waste treatment pH, and eventually be disposed of in landfill with other waste sludge. However, due to the expected high water solubility, about 50% will stay in the water column. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified chemical contained in sludge or in papers disposed of directly through normal garbage.

Following its use in Australia, it is assumed that 50% of notified chemical will eventually be released into the aquatic environment as a result of the paper recycling process. A calculated worst-case scenario daily PEC in the sewer effluent is 0.34 µg/L. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer, (3) there is no adsorption or degradation in the sewer prior to release.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified chemical in rural areas and coastal water may approximate 0.34 and 0.034 µg/L, respectively.

Incineration of the waste paper will destroy the notified chemical with the generation of water vapours and oxides of carbon, nitrogen, sulphur, and sodium.

Except for paper recycling, the notified chemical is not expected to enter the aquatic environment. In any case, the notified chemical's high water solubility is unlikely to result in bioaccumulation.

**9.1.2. Environment – effects assessment**

The results of the ecotoxicological data indicate that the notified chemical is practically non-toxic to fish with an acute 96 LC50 of >100 mg/L. The Predicted No Effect Concentration (PNEC) is 100 μg/L, using a safety factor of 1000, as toxicity data are available for only one trophic level.

**9.1.3. Environment – risk characterisation**

The risk quotients indicate an acceptable risk (Q<0.0034) for both marine and freshwater organisms.

Given the diffuse and widespread use of the ink product, the concentration of the notified chemical in the aquatic compartment is likely to be low. Furthermore, the low Q values indicate that there is unlikely to be an environmental risk to the aquatic compartment.

It is expected that any waste generated during use will be disposed of by incineration or to landfill. In landfill the notified chemical contained in sludge or in papers will degrade slowly via biotic or abiotic processes. Therefore, environmental risk from the reported use pattern of the notified chemical s likely to be low.

**9.2. Human health**

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

The most likely exposure route for the notified chemical is dermal or accidental ocular exposure by means of ink-containing cartridges (containing <5% notified chemical) or via printed-paper containing trace amounts <0.5 mg of notified chemical per printed page. *Importation, storage, transport and distribution*

The notified chemical will be imported in pre-packed sealed cartridges. Waterside, warehouse and transport/distribution workers are not expected to be exposed to the notified chemical unless the packaging is breached.

*Office workers and service technicians*

Intermittent dermal or accidental ocular contact (<5% notified chemical) may occur if residues of the ink containing the notified chemical are left in the printer or on the cartridge. Office workers and service technicians may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, repairing or maintaining printers.

Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Printer maintenance personnel often wear cotton disposable gloves. Pre-packed ink cartridges are sealed.

Trace amounts of the ink may be lifted off the printed page during handling. Therefore, dermal contact with ink containing the notified chemical by means of deposits on the printed paper is possible. However, such exposure is expected to be low because of the notified chemical is sorbed and bound to the paper matrix. Once the ink has dried on the printed page, the notified chemical will be unavailable for human contact. Some intermittent exposure may occur if printing onto a non-absorbent substrate occurs and the ink does not dry for a time.

Based on the described use pattern, occupational exposure to the notified chemical is assessed as low.

**9.2.2. Public health – exposure assessment**

From the point of importation to the end use of the ink preparation containing the notified chemical, the ink preparation is either enclosed in a cartridge made for insertion in ink jet

printers or is present on printed paper in a cured state. Public exposure through importation, transportation or storage is assessed as negligible.

There is little potential for exposure to the notified chemical during print cartridge changes. Any exposure to the ink preparation that does occur is most likely to be dermal and of a minimal and transient nature. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available. Once the ink has dried on the printed page, the notified chemical will be unavailable for human contact.

Intermittent dermal or accidental ocular contact may occur if residues of the ink containing the notified chemical are left in the printer or on the cartridge. Trace amounts of the ink may be lifted off the printed page during handling; therefore, dermal contact with ink deposited onto paper is possible.

Ink products containing the notified chemical are fully contained within inkjet cartridges and are inserted directly into inkjet printers. Public exposure may result from contact with ink residues deposited within the printer particularly during cartridge replacement or printer maintenance. When using the cartridges, consumers may make dermal contact with the ink preparation containing the notified chemical where an attempt is made to repair some mechanical mishap involving the cartridges in the printer.

Assuming up to 0.5 mg of notified chemical per A4 page, a worst case of 50% transfer of undried notified chemical to fingers and the relative areas of finger ends and paper size, it is estimated that potential removal is < 1% of the applied notified chemical in each event.

Area of contact with finger ends (four fingers on one hand) = 8 $cm^2$
A4 sized paper substrate = ca. 600 $cm^2$

% Removal = (8/600) × 0.5 × 100 = < 1%

Therefore total removal to finger ends at point of contact would be < 1% of 0.5 mg notified chemical per event = < 0.005 mg. Assuming 10 events per day, exposure may be up to 0.05 mg/day.

A worst-case estimate of body burden of 0.0007 mg/kg/day is based on transfer of 0.005 mg/day, assuming no washing between events for a 70 kg person and 100% absorption, would be < 0.005 × 10/70 = ca. 0.0007 mg/kg/day. It is noted that the estimate based on 100% absorption is conservative, given that the notified chemical is not readily bioavailable.
Based on the described use pattern, public exposure to the notified chemical is assessed as low.

### 9.2.3. Human health - effects assessment

The notified chemical has a molecular weight only slightly less than 1000 and a low octanol/water partition coefficient, indicating a low degree of lipophilicity and low potential to cross biological membranes.

The notified chemical is of low acute oral toxicity in rats and is irritating to the skin and eyes in rabbits. It is neither a skin sensitiser in a mouse local lymph node assay nor a mutagen in an Ames test. In the skin irritation study, no oedema was observed. However, red to purple colouration of the skin, which could have masked possible slight to well-defined erythema in this study, was observed in two animals up to day 10 and in one animal up to day 13. Therefore, the skin irritation effect is classified based on the persistent colouration.

Based on the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999), the notified chemical is classified as a hazardous substance and assigned the symbol Xi "irritant".

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

The notified chemical has a low order of acute toxicity and is not a skin sensitiser. The notified chemical was found to be an eye and skin irritant.

Exposure during normal handling of the cartridge is not expected through use of containment, other than in the unlikely event that the printer/photocopier cartridge is faulty. Given the low intrinsic health hazard of the notified chemical in the ink formulation that is not classified as hazardous, the occupational health risk arising from use of cartridges containing the notified chemical is expected to be minimal.

Based on the facts that the concentration of the notified chemical in the ink is low in the ink cartridge (<5% notified chemical), the ink remains in the inkjet cartridge with little likelihood of leakage or rupture, and the ink is bound to the paper on which it is deposited, ingestion of the notified chemical which could result in toxic effects in humans will unlikely occur. However, caution should be taken by the office workers and service technicians to avoid any ingestion occurring or accidental eye contact.

The amount of the notified chemical to which a worker may be exposed is low, both because of the low amount involved in a likely contact scenario, and because the concentration of the notified chemical in the ink is less than 5%. Following printing application, the notified chemical will become bound to paper and will not be bioavailable. Proper instructions in the handling of inks cartridges, particularly in clean-up procedures in the event of accident, are given to workers via Material Safety Data Sheets (MSDSs), labels and instruction manuals.

Based on the described use pattern, the health risk to workers is considered to be low.

### 9.2.5. Public health – risk characterisation

There will be no significant public exposure to the notified chemical given the low concentration in the ink product in the cartridges and the design of the cartridges. Contact with residue on the printer's internal workings will be very small. Contact with printed paper is unlikely to lead to significant dermal exposure, as the notified chemical will be bound to the paper. There is unlikely to be any public health risk posed by the notified chemical.

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. The notified chemical is present at low concentrations in a formulation that is not classified as hazardous.

There is a very slight chance of ingestion of the notified chemical due to accidental rupture of a cartridge. As a worst-case scenario, a 10 kg child ingesting 5 mL of a 5% solution would receive a dose of approximately 27.65 mg/kg which is significantly below the lethal dose ($LD_{50}$ > 2000 mg/kg). The notified chemical has a low acute oral toxicity and the quantities consumed would be minimal, so the notified chemical is unlikely to pose a significant risk to human health.

Therefore, based on the low hazard and low potential for exposure, the risk to public health from exposure to the notified chemical is considered 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 classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Irritant (Xi): R36/ 38 (Irritating to eyes and skin).

As a comparison only, the classification of 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 irritation | 3 | Causes mild skin irritation |
| Eye irritation | 2A | Causes serious eye irritation |

### 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 No Significant Concern to public health based on its reported use pattern.

## 11. MATERIAL SAFETY DATA SHEET

### 11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). The MSDS for a product containing the chemical 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 product containing the 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

REGULATORY CONTROLS

Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - *Irritant* (Xi): R36/ 38 (Irritating to eyes and skin).

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Concentration cut-off ≥20%: R36/ 38 (Irritating to eyes and skin).

CONTROL MEASURES

Occupational Health and Safety

No special precautions are required for the notified chemical when used at low quantities in inkjet printer cartridges. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Personnel should wear cotton or disposable gloves when servicing printers and refilling cartridges.

  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.
- Avoid contact with the eyes and skin.
- 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 by incineration or landfill.

Emergency procedures

No special precaution necessary (cartridges).

### 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(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 any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

## 13. BIBLIOGRAPHY


Australian Environmental Review (2001). On track for best ever recycling rates. 16(1), 16.

CIT (2001) M-1114, Bacterial reverse mutation test, Laboratory study number 21772 MMT, CIT, France (unpublished report, provided by the notifier).

CIT (2002a) M-1114, Water Solubility, Laboratory study number 22899 PSE, CIT, France (unpublished report, provided by the notifier).

CIT (2002b) M-1114, Estimation of the partition coefficient ($P_{ow}$), Laboratory study number 22900 APC, CIT, France (unpublished report, provided by the notifier).

CIT (2002c) M-1114, Acute oral toxicity in rats, Laboratory study number 21768 TAR, CIT, France (unpublished report, provided by the notifier).

CIT (2002d) M-1114, Acute dermal irritation in rabbits, Laboratory study number 21769 TAL, CIT, France (unpublished report, provided by the notifier).

CIT (2002e) M-1114, Acute eye irritation in rabbits, Laboratory study number 21770 TAL, CIT, France (unpublished report, provided by the notifier).

CIT (2002f) M-1114, Skin sensitisation test in guinea pigs, Laboratory study number 21771 TSG, CIT, France (unpublished report, provided by the notifier).

CIT (2002g) M-1114, Evaluation of skin sensitisation potential in mice using the local lymph node assay (LINA), Laboratory study number 22627 TSS, CIT, France (unpublished report, provided by the notifier).

CIT (2002h) Activated sludge, respiration inhibition test. Laboratory study No. 22901 EAS, CIT, France (unpublished report, provided by the notifier).

CIT (2004) Acute toxicity in the rainbow trout under static conditions Laboratory study number 26722 EAP, CIT, France (unpublished report, provided by the notifier).

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

SEPC (2002a) M-1114, Melting point, Report No. 01-902003-099, SEPC, France (unpublished report, provided by the notifier).

SEPC (2002b) M-1114, Falmmability of solids, Report No. 01-902003-101, SEPC, France (unpublished report, provided by the notifier).

SEPC (2002c) M-1114, Boiling point, Report No. 01-902003-100, SEPC, France (unpublished report, provided by the notifier).

SEPC (2002d) Determination of ready biodegradability. Carbon dioxide ($CO_2$) evolution (Modified Sturm Test), Report No. 01-902003-102, SEPC, France (unpublished report, provided by the notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.