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

FULL PUBLIC REPORT

K-1334

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**K-1334****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

ILFORD Imaging Asia Pacific Pty Limited (ABN 69 004 283 701)
Unit 1/10 Duerdin Street
Clayton North VIC 3168

and

Hewlett-Packard Australia Pty Ltd (ABN 74 004 394 763)
31-41 Joseph Street
Blackburn VIC 3130

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:

Identity of chemical;
Composition; and
Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Flash point;
Particle size;
Flammability limits;
Autoignition temperature; and
Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (PMN), Canada (Schedule 1), Europe (VII notification), Japan (low volume notification),
Switzerland (free of poison class), China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

K-1334

3. COMPOSITION

DEGREE OF PURITY

High

4. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported as a component of pre-packed inkjet cartridges of 25 to 55 mL capacity. The inks will contain a maximum of <10% w/w notified chemical.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Kilograms</i>	100-1000	100-1000	100-1000	100-1000	100-1000

USE

As a dye in inks for use in inkjet printers.

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 Limited (ABN 69 004 283 701)

Unit 1/10 Duerdin Street

Clayton North VIC 3168

and

Hewlett-Packard Australia Pty Ltd (ABN 74 004 394 763)

31-41 Joseph Street

Blackburn VIC 3130

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as pre-packaged cartridges. The imported cartridges containing the notified chemical may be transported by road to their distribution location.

5.2. Operation Description

No reformulation or repackaging of the product occurs in Australia. The sealed ink-jet cartridge is delivered to the end-user in its original packaging. Service technicians and office workers will handle the ink jet cartridge when replacing spent cartridges in the printer.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Delivery from wharf	10	4h/day	40 days/year
Distribution (Storage and Transport)	100	6h/day	240 days/year
Service Technicians and Office workers	Approx 10000	Approx 10 minutes	Approx 20 days/year

Exposure Details

Office workers and service technicians will replace spent ink cartridges. Replacement of printing cartridges involves removal of the old printing cartridge from the printing machine and directly loading the new cartridge. These workers may have dermal contact with small quantities of the notified chemical as a result of touching the print heads while replacing cartridges, or on handling printed paper or film, 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 has dried the notified chemical is bound to the paper matrix and is not expected to be readily bioavailable.

Trained service technicians will maintain and clean printing machines.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured or reformulated in Australia. The notified chemical will be imported as pre-packaged cartridges.

RELEASE OF CHEMICAL FROM USE

Releases are not expected during the changing of inkjet cartridges. Virtually all of the notified chemical will eventually be released to the environment. The majority of the notified chemical will be bound to printed paper which will either be buried in landfills, incinerated or released from effluent deinking processes. Recycling of treated paper could result in release of a proportion of the notified chemical to the aquatic compartment. However, the environmental concentration is expected to be negligible. Where recycling does not occur the notified chemical will be disposed of to landfill where it is expected to remain bound to paper.

Used cartridges containing 0.1% of the ink will either be disposed of to landfill.

5.5. Disposal

The majority of the notified chemical will either be disposed of to landfill or incinerated. Small amount may also be released to sewer as a result of paper recycling processes.

5.6. Public exposure

The notified chemical will not be manufactured, reformulated or packaged in Australia. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. Contact with very small quantities of ink during changing cartridges or on handling incompletely dried printed material may occur.

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

6. PHYSICAL AND CHEMICAL PROPERTIES

The following physico-chemical properties are for the notified chemical unless otherwise indicated.

Appearance at 20°C and 101.3 kPa		Black powder
Melting Point		Not determined
METHOD	OECD TG 102 Melting point/Melting range EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. Thermogravimetric analysis (ATG)	
Remarks	The thermogravimetric analysis has shown a slight degradation of the test item between 70°C and 260°C, and high degradation from 260°C.	
TEST FACILITY	Societe d' Ecotoxicologie et de Physico-Chimie (SEPC) (2000a)	
Density		1776 kg/m ³ at 20°C
METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.	
TEST FACILITY	Paradis Bertrand Defitraces (2002)	
Vapour Pressure		Not determined.
Remarks	Based on the chemical structure ie a high molecular weight tetrasodium salt, the notified chemical is unlikely to have a significant vapour pressure.	

Water Solubility >200 g/L at 20°C

METHOD	OECD TG 105 Water Solubility (Flask Method). EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Analytical Method: HPLC Approximately 3.75 g of test substance was added to 5 mL of water and agitated at 30°C for 24-72 h. Samples were cooled to 20°C for 24 h after which a visual assessment of saturation was made. This was also done at 200, 500 and 1000 g/L.
TEST FACILITY	Centre International de Toxicologie (CIT) (2001a)

Hydrolysis as a Function of pH

METHOD	EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
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<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2}
4	25	415 h
7	25	>1 year
9	25	>1 year

Remarks	Less than 10% degradation of the test substance was observed after 5 days at the two higher pH values of 7.0 and 9.0. At pH 4.0 the test material showed greater than 10% hydrolysis after 5 days in the preliminary test. The hydrolysis at this pH was then examined at three different temperatures (50, 60, and 80°C) and extrapolated to 25°C.
TEST FACILITY	Centre International de Toxicologie (CIT) (2003a)

Partition Coefficient (n-octanol/water) log Pow at 20°C = <-3.3

METHOD	OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method. EC Directive 92/69/EEC A.8 Partition Coefficient.
REMARKS	The partition coefficient was estimated from the ratios of the concentrations of the test substance in the pure solvents (Pow = saturation C _{n-octanol} / saturation C _{water}). The water solubility was taken from the determination of water solubility test above and the n-octanol solubility was estimated by shaking samples of the test material in n-octanol and assessing visually. Note no samples were injected into an HPLC and the study consisted only of the preliminary test.
TEST FACILITY	Centre International de Toxicologie (CIT) (2001b)

Adsorption/Desorption log K_{oc} = -0.52 (calculated).

METHOD	QSAR taken from the Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances
Remarks	The equation for nonhydrophobics was chosen: Log K _{oc} = 0.52 × log K _{ow} + 1.2 The value of Log K _{ow} used was the value calculated in the above report. The result should be treated with some caution as it is unclear how relevant the equation used is for this rather unusual structure.
TEST FACILITY	Centre International de Toxicologie (CIT) (2003b)

Dissociation Constant Not Determined

Remarks	The notified chemical contains sodium salts of sulfonic acid moieties which are
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very strong acids and as such is expected to remain totally dissociated throughout the entire pH range (4-9).

Particle Size Not determined

Remarks The notified chemical will be imported as an aqueous solution.

Flash Point >93.3°C (ink product)

Remarks Test report not provided.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY Societe d' Ecotoxicologie et de Physico-Chimie (SEPC) (2000b)

Explosive Properties Not explosive

Remarks Test report not provided.

Reactivity

Remarks The notified chemical is stable under normal conditions of use. It is reactive with strong oxidising agents.

7. TOXICOLOGICAL INVESTIGATIONS

Limited toxicity data were submitted for the notified chemical and are described below.

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	inadequate evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Purified water
Remarks - Method	No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	2000	1

LD50 >2000 mg/kg bw
Signs of Toxicity Black colouration of the snout, ears and tails in all surviving animals..
Effects in Organs No abnormalities were observed, except for black colouration of all the organs of a male animal that died on day 2.
Remarks - Results Signs of hypoactivity or sedation were observed prior to the death of one male on day 2. Body weight gain for surviving animals was comparable to historical control animals.

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

TEST FACILITY Centre International de Toxicologie (CIT) (2000a)

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

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 males
Vehicle Purified water
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations.

RESULTS
Remarks - Results No cutaneous reactions were observed during the study, except for a slight black colouration of the treated skin noted at 1-hour observation. All scores were zero for erythema and oedema.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Centre International de Toxicologie (CIT) (2000b)

7.5. 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 males
Observation Period 6 days
Remarks - Method No significant protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	-	-	-	1	5 days	0
<i>Conjunctiva: chemosis</i>	2.0	0.3	1.3	3	5 days	0
<i>Discharge</i>	0	0	0	2	1 hour	0
<i>Corneal opacity</i>	1.3	0	0	2	5 days	0
<i>Iridial inflammation</i>	0.66	0	0	1	48 hours	0

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

– mean scores not calculated; scoring obscured by black colouration for up to 24 hours

Remarks - Results

Very slight to moderate conjunctival reactions were noted in all animals with chemosis in 2/3 animals and redness in 1/3 animals persisted up to 5 days. A black colouration of the conjunctiva was noted in all animals and obscured the scoring of conjunctival redness of up to 1 day. A clear discharge, which was evident at the 1-hour observation period, was also noted in all animals. A slight iritis was noted in 1/3 animals. Corneal opacity, which persisted up to 5 days was noted in 2/3 animals.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

Centre International de Toxicologie (CIT) (2000c)

7.6. Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation – maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitization – maximisation test.

Species/Strain

Guinea pig/Hartley CrI: (HA)BR

PRELIMINARY STUDY

Maximum Non-irritating Concentration:

intradermal: 5% (w/w)

topical: 30% (w/w)

MAIN STUDY

Number of Animals

Test Group: 10/sex

Control Group: 5/sex

INDUCTION PHASE

Induction Concentration:

intradermal injection 5% (w/w)

topical application 30% (w/w)

Signs of Irritation

A discrete or moderate erythema was observed in 5/20 animals, which persisted up to 48 hours in 1 animal. Dryness of the skin was also observed in 2/20 animals. The test substance tinted the skin black in all animals obscuring possible erythema in 2/10 control animals and 3/20 treated animals.

CHALLENGE PHASE

1st challenge

topical application: 30 (w/w)

Remarks - Method

The test substance did not show irritation during preliminary test. Therefore, on day 7 of the induction phase, the animals were treated with sodium lauryl sulphate to induce local irritation.

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1st challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	30%	5/20	1/20
<i>Control Group</i>	30%	0/10	0/10

Remarks - Results No clinical signs or death were observed during the study. A black colouration was noted in control and treated animals, which prevented observation of possible discrete and moderate erythema in some animals.

CONCLUSION There was limited evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Centre International de Toxicologie (CIT) (2000d)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity (Escherichia coli/Salmonella typhimurium - Reverse Mutation Assay)
Plate incorporation procedure/Pre incubation procedure

Species/Strain *S. typhimurium*:
TA98, TA100, TA102, TA1535, TA1537.
E. coli: WP2 uvrA.

Metabolic Activation System Arochlor 1254 – induced rat liver S9 fraction

Concentration Range in Main Test a) With metabolic activation: 62.5 to 1000 µg/plate.
b) Without metabolic activation: 62.5 to 1000 µg/plate.

Vehicle Distilled water

Remarks - Method A preliminary study was conducted on TA98, TA100, TA102 and WP2uvrA with and without S9 using test concentrations 0 to 5000 µg/plate. A slight to strong black colouration was observed in petri plates at dose levels ≥ 100 µg/plate. At 2500 µg/plate, the strong colouration interfered with the analysis of the plates. No precipitates were noted and toxicity was not observed at concentrations up to 5000 µg/plate.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	None	None	None	62.5 µg/plate
Test 2	-	None	None	None
<i>Present</i>				
Test 1	None	None	None	None
Test 2	-	None	None	None

Remarks - Results A mutagenic effect was noted in TA1535 (up to 2.68 fold of control in Test 1) without metabolic activation. This increase was an isolated event, which did not demonstrate a dose response, and was not reproduced; therefore it is not considered of biological significance. No precipitation or cytotoxicity was observed.

Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.

CONCLUSION

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

TEST FACILITY

Centre International de Toxicologie (CIT) (2000e)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 301 B Ready Biodegradability: Modified Sturm, CO₂ Evolution Test.

Inoculum

Aerobic activated sludge.

Exposure Period

28 days.

Auxiliary Solvent

None.

Analytical Monitoring

Back titration of a titre of Ba(OH)₂ from the CO₂ traps with HCl.

Remarks - Method

Inoculum was aerated overnight in culture medium prior to the addition of test materials. Samples were collected from the first CO₂ absorber vessel on Days 1, 4, 6, 8, 11, 14, 18, 21, 22, 25 and 29. On day 28 test vessels were treated with 1 mL of concentrated hydrochloric acid to drive off any inorganic carbonates formed.

RESULTS

<i>Test substance</i>		<i>Sodium Acetate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
28	12.36	28	87.42

Remarks - Results

The extent of degradation of the reference material validates the test. A toxicity control containing test material and sodium acetate reached 29% degradation on day 28 indicating that the notified chemical is not toxic to sewage treatment organisms since >25% was achieved.

CONCLUSION

The new compound is not readily biodegradable under the conditions of the test.

TEST FACILITY

Centre International de Toxicologie (CIT) (2000f)

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical were not provided for this notification. The notified chemical has a high molecular weight and water solubility and low partition coefficient suggests that it is unlikely to cross biological membranes and bioaccumulate (Connell, 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static test. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static test.
Species	<i>Onchorhynchus mykiss</i>
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	151 mg CaCO ₃ /L
Analytical Monitoring	HPLC
Remarks – Method	Water quality parameters of pH, water temperature, O ₂ content were within normal limits throughout study. Measured concentrations were within 20% of nominal

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		0 h	24 h	48 h	72 h	96 h
0		7	0	0	0	0	0
0.1		5	0	0	0	0	0
1		5	0	0	0	0	0
10		5	0	0	0	0	0
100	102	7	0	0	0	0	0

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	The results of the study showed that no mortalities or sub-lethal effects were observed in any of the test vessels. The 96-hour EC ₅₀ for the notified chemical to <i>Oncorhynchus mykiss</i> is greater than 100 mg/L.

CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to fish.
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TEST FACILITY	Centre International de Toxicologie (2001c)
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9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Release of the ink containing the notified chemical to the environment is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the ink will be contained and presumably disposed of in landfill. Environmental exposure will result from the disposal of printed-paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Ink residues contained in the empty cartridges are expected to be about 2% of the import volume and to remain within these containers, although release could occur from deterioration of the cartridge.

The total import volume of the notified chemical will ultimately be disposed of in either landfill or be incinerated or recycled with paper. Waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. While not readily biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the compound. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, sulphur and nitrogen.

In addition to landfill, some of the ink printed on paper will enter the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes are expected to go to trade waste sewers. 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.

In an worst-case situation where the maximum range of import volume is used (i.e. 1 tonne) and assuming that 10% of this quantity is released to the sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 0.27 kg/day. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.07 µg/L.

Maximum amount entering sewer annually	100 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	0.07 µg/L (0.07 ppb)

The substance is not expected to bioaccumulate due to its high water solubility. (Connell 1990). Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. As a consequence of its anionic nature, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments.

Fate

The substance is not expected to bioaccumulate due to its high water solubility. (Connell, 1990).

Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. As a consequence of its anionic nature, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments.

9.1.2. Environment – effects assessment

The only toxicity result is for fish (>100 mg/L) and indicates the notified substance is practically non-toxic to fish. A predicted no effects concentration (PNEC) can be determined when at least one acute LC50 is available (eg. fish, *Daphnia* or algae). The PNEC is calculated by taking the LC50 value and dividing this value by an assessment safety factor of 1000 (OECD) for a single toxicity endpoint. This would give a PNEC value of 0.1 µg/L.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for 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, release of the notified chemical to the environment is expected to be low but 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 0.7. This value is less than 1, indicating no immediate concern to the aquatic compartment. Additionally, this value is an over estimate and 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 and the only toxicity value is a limit value with the true LC50 being >100 mg/L.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Office workers and customer service engineers may be intermittently exposed to the notified chemical contained in the cartridge when replacing spent ink cartridge, and during repair, maintenance and cleaning of printers. Customer service engineers may potentially come in contact with the notified chemical more often than office workers. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Customer service engineers are trained and will wear cotton disposable gloves. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

Exposure may occur upon handling printed matter. However, very little printing ink is used per sheet of paper and it would not be separately available for exposure or dermal uptake as it is fused and fixed to the printed surface.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

9.2.2. Public health – exposure assessment

The printing ink will be available for use in home printers. The public will have dermal exposure to the notified chemical in the printing ink when inserting or removing a damaged cartridge and clearing paper jams. The ink is contained in the cartridge and the physical design of the cartridge prevents leakage of ink and prevents handlers from dermal exposure.

Public exposure will also occur by dermal contact with printed media treated with ink containing the notified chemical.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral toxicity in rats. It was non-irritating to skin and a slight eye irritant in rabbits. Very slight to moderate conjunctival reactions, corneal opacity and slight iritis were noted in all animals, which resolved by day 6. In an adjuvant study in guinea pigs, treated animals showed inadequate evidence of skin sensitisation. A black colouration was noted in control and treated animals, which prevented observation of possible erythema in some animals. The notified chemical was not mutagenic in bacteria in the absence and presence of metabolic activation. No precipitation or cytotoxicity was observed. On the basis of the data supplied, the notified chemical would not be 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 loading and removal of a cartridge into or from its containment area in a printer can be readily accomplished without any contact with the 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 remaining ink contained within the spent cartridge cannot be removed without breaking the cartridge. Ink on paper will be bound to the paper and is unlikely to be transferable to a person's skin. Although the notified chemical is described as solid (powder) in appearance, it is imported in a liquid form and therefore exposure to dust or powder is not anticipated.

Overall, the risk of adverse health effects arising from exposure to the notified chemical is low due to its expected low toxicity, low concentration in the printing inks and low potential for exposure. The use of disposable gloves by maintenance workers and the presence of adequate ventilation in the workplace would ensure that the occupational risk posed by the notified chemical is low when used as specified in the notification. In addition, the occupational health risk to waterside, warehouse and transport workers is negligible, considering the small quantities in individual ink cartridges, and the low hazard presented by the chemical and that the package are handled intact by these workers.

9.2.5. Public health – risk characterisation

There is low potential for public exposure to the notified chemical during transportation,

handling and usage of the printing ink unless accidental spillage occurs. Given the low concentration of the notified chemical in the printing inks and the low potential for exposure, the risk from public 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*.

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 when used as a component of printing ink.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the 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 products 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

CONTROL MEASURES

Occupational Health and Safety

No special precautions are required for the notified chemical when used at low quantities as a component of ink cartridges for printers. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed for use of printing inks containing the notified chemical:

- Avoid contact with skin.
- Printers should be located in well-ventilated areas.
- Service personnel should wear cotton or disposable gloves when replenishing spent ink cartridges and servicing printers.

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 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

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
 - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained and collected for disposal in landfill. Do not allow this strongly coloured substance to enter drains.

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

Connell, D.W. (1990). General Characteristics of Organic Compounds Which Exhibit Bioaccumulation. In: Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA, pp. 47-57.

Centre International de Toxicologie (CIT) (2000a) Acute Oral Toxicity in Rats. Study No. 20275 TAR. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2000b) Acute Irritation in Rabbits. Study No. 20276 TAL. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2000c) Acute Eye Irritation in Rabbits. Study No. 20277 TAL. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2000d) Skin Sensitisation Test in Guinea Pigs. Study No. 20278 TSG. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2000e) Bacterial Reverse Mutation Test. Study No. 20474 MMT. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2000f) Determination of Ready Biodegradability CO₂ Evolution Test. Study No. 20323 ECS. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2001a) Water Solubility. Study No. 20312 PSE. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2001b) Estimation of the Partition Coefficient (Pow) using High Performance Liquid Chromatography (HPLC) Method. Study No. 20313 APC. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2001c) Acute Toxicity in the Rainbow Trout Under Static Conditions. Study No. 21416 EAP. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2003a) Determination of the Abiotic Degradation (Hydrolysis as a Function of pH). Study No. 25014 PDA. CIT Centre International de Toxicologie, Evreux, Cedex, France.

Centre International de Toxicologie (CIT) (2003b) Determination of the Koc Value. Study No. 25444 PPC. CIT Centre International de Toxicologie, Evreux, Cedex, France.

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

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

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Paradis Bertrand Defitraces (2002) Relative Density – Stereopycnometer Method. Study No. 02-902003-068. Paradis Bertrand Defitraces, Brindas, France.

Societe d' Ecotoxicologie et de Physico-Chimie (2000a) Melting Point Study No. 00-902003-022. Societe d' Ecotoxicologie et de Physico-Chimie, Cedex, France.

Societe d' Ecotoxicologie et de Physico-Chimie (2000b) Flammability of Solids. Study No. 00-902003-024. Societe d' Ecotoxicologie et de Physico-Chimie, Cedex, France.