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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Red 003

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd. (ABN: 74 004 394 763)
3 Richardson Place
North Ryde
NSW 2113

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- Other names
- CAS Number
- Molecular formula
- Structural formula
- Molecular weight
- Spectral data
- Purity
- Identity of toxic or hazardous impurities
- % weight of toxic or hazardous impurities
- Non-hazardous impurities
- Identity of additives and adjuvants
- % weight of additives/adjuvants
- Import volume
- Concentration of notified chemical in ink
- Volume of cartridge
- Identity of sites

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
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Red 003

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD Infrared (IR) spectroscopy

Remarks	Reference spectrum provided
TEST FACILITY	Dainippon ink and Chemicals, Inc. (2005)

ANALYTICAL METHOD	^{1}HNMR spectrum
Remarks	Reference spectrum provided

ANALYTICAL METHOD	Mass spectrum
Remarks	Reference spectrum provided
TEST FACILITY	Dainippon ink and Chemicals, Inc. (2004)

3. COMPOSITION

DEGREE OF PURITY
<90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia, but will be imported as a component of inkjet printing inks in pre-packed cartridges. The inks will contain <1% of the notified chemical.

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

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

USE
The notified chemical acts as a component of printing ink designed for use in office printers, printers used by professional photographers, printing service businesses, and in printing kiosks at the shopping malls.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney/Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
No manufacture or reformulation of the notified chemical will occur in Australia. The ink cartridges containing the notified chemical will be imported and stored at the notifier's warehouses in NSW and Victoria prior to distribution to end users.

TRANSPORTATION AND PACKAGING
The size of the imported ink cartridges will be 30-790 mL. At port of entry, the cartridges would be normally transferred by land to the notifier's warehouses and then distributed by road to end users. No repackaging occurs.

5.2. Operation description

No reformulation, repackaging, filling or refilling of the cartridges containing the notified chemical, or any other handling of the notified chemical is carried out in Australia. Sealed ink cartridges containing the notified chemical will be distributed to end user sites and handled by service technicians, office workers or the public, who will replace spent cartridges in the printers as necessary.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number (Approx.)*	*Exposure Duration (Approx.)*	*Exposure Frequency (Approx.)*
Importation/ Waterside	5-10	4 h/day	50 days/year
Storage and Transport	3	2 h/day	50 days/year
Office worker	1000	5-10 min/day	10 days/year
Service Technicians	10	8 h/day	230 days/year

Exposure Details

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

Service technicians
Service technicians may be exposed to the ink containing <1% of the notified chemical during repair and cleaning of ink jet printers. Exposure to the notified chemical may occur while removing cartridges if the ink is inadvertently handled. Dermal exposure is expected to be the main potential route of exposure. Although generation of aerosols from the printing ink is possible during printing, they may not escape from inside the printer.

Office workers
Exposure while changing cartridges is expected to be limited to dermal exposure, occurring if the ink is inadvertently touched. However, this would be avoided by users and would be evident if it occurred. Similarly, occasional dermal exposure during use of the printer could occur if the printed pages were touched inadvertently before the ink dried, or if ink-stained parts of the printer were touched. Such exposure is expected to be low and to be avoided by workers. Furthermore, the notified chemical is bound to the paper matrix and not expected to be readily bioavailable except if the paper or other substrate is ingested.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release is expected as manufacture and reformulation of the notified chemical will not take place in Australia.

RELEASE OF CHEMICAL FROM USE
Release of the ink solution to the environment is not expected under normal use because the cartridges are designed to prevent leakage. If leakage or accidental spills occur when changing the spent cartridges for new cartridges, the ink will be contained with absorbent material, which will presumably be disposed of in a landfill.

Empty cartridges will be recycled. The cartridges will be crushed and the various parts recycled. Ink residues, estimated as <10% of the ink, will be separated from the cartridge and incinerated.

Recycling of treated paper may take place in a number of centres throughout Australia. 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, therefore, 30%-60% of the notified chemical in the recycled paper will be disposed of with sludge in a landfill. The remainder of the notified chemical can be expected to go to trade waste sewers and be released to the aquatic environment. Based on the low concentration of the notified chemical on the paper, and that the paper recycling centres are located throughout Australia, the release of the notified chemical to the aquatic environment will be in a highly diffuse manner, with most of the notified chemical reporting to the sludge due to its low water solubility.

5.5. Disposal

The notified chemical enclosed in cartridges can be disposed of directly by landfill. It can also be disposed of indirectly from waste paper containing the notified chemical via recycling, to landfill or by incineration.

5.6. Public exposure

The notified chemical will be used in inks designed for use in printing kiosks at the shopping malls. The public will use the printing kiosks only. The public could be exposed from use of the kiosks if they handle the printed papers before it is adequately dry. After the paper is dry, the notified chemical is bound to the paper matrix and not expected to be bioavailable.

The public may be exposed to the notified chemical in the unlikely event of an accident during transportation of the cartridges if the cartridges suffer extensive breaking.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Red powder

Melting Point/Freezing Point Decomposed prior to melting from approximately 322°C.

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature
TEST FACILITY Safepharm Laboratories Ltd (2005b)

Boiling Point Not determined

Remarks The test material decomposes prior to melting.

Density 1600 kg/m^3 at 20.4 ± 0.5°C

METHOD EC Directive 92/69/EEC A.3 Relative Density
Remarks Relative density was calculated as 1.6.
TEST FACILITY SafePharm Laboratories Ltd (2005a)

Vapour Pressure 1.4 x 10^{-16} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure
Remarks The test material did not change in appearance under the conditions used (vapour pressure balance at 240-250°C) in the determination.
TEST FACILITY SafePharm Laboratories LTD (2005c)

Water Solubility < 8.92 × 10^{-6} g/L at 20.0°C± 0.5°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility
Remarks Analytical Method: HPLC. The column elution method was used after a preliminary shake flask test showed very low solubility. The definitive test could not detect any notified chemical.
TEST FACILITY Safepharm Laboratories Ltd (2005b)

Hydrolysis as a Function of pH Not determined

Remarks The test was not carried out as the test material is essentially insoluble in water (water solubility less than 8.92 x 10^{-6} g/L). Method C7 states that it is only applicable to water soluble substances.

The test material contains no functional groups that are prone to hydrolysis. Therefore the test material can be expected to be hydrolytically stable under environmentally relevant conditions.

TEST FACILITY SafePharm Laboratories Ltd (2005a)

Partition Coefficient (n-octanol/water) log Pow at 20°C = > 4.17

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks >98.7% of the notified chemical eluted after 4 of the 7 reference materials, but as a number of peaks. Analytical Method: HPLC.
TEST FACILITY Safepharm Laboratories Ltd (2005b)

Adsorption/Desorption log K_{oc} = > 4.19

METHOD EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using HPLC (Screening method)
Remarks The test proved to be unsuitable. Therefore an estimation of log10Koc was obtained by calculation using QSARs ($log_{10}K_{OC}$ = 0.52 $log_{10}P_{OW}$ + 1.02). This correlated well with the preliminary HPLC result.
TEST FACILITY SafePharm Laboratories LTD (2005a)

Dissociation Constant Not determined

Remarks The test material contained no modes of dissociation within the range and scope of the method.
TEST FACILITY SafePharm Laboratories (2005a)

Particle Size The results are showed in the table below.

Measurement	*Method*	*Result*
Proportion of test material having an inhalable particle size[1] less than 100 μm	Sieve	4.50%
Proportion of test material having a thoracic particle size[2] less than 10.2 μm	Cascade Impactor	4.29%
Proportion of test material having a respirable particle size[3] less than 5.4 μm	Cascade Impactor	0.96%

[1] The inhalable particle size is defined as the mass fraction of particles which can be inhaled by nose or mouth.
[2]The thoracic particle size is defined as the mass fraction of particles that passes the larynx.
[3]The respirable particle size is defined as the mass fraction of particles that reaches the alveoli.

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions
Remarks A Screening test (Sieve Method) and a Definitive test (Cascade Impactor Method) were conducted.

Too few particles were of a size less than 10.2 μm to allow accurate assessment of mass median aerodynamic diameter.

Representative sampling was ensured by rolling the sample container for approximately 10 minutes and sampling from the top, middle and bottom prior to the definitive test.
TEST FACILITY SafePharm Laboratories (2005a)

Flash Point Not determined

Remarks The notifier justified that the notified chemical is a solid and non-flammable.

Flammability Limits Non flammable

METHOD EEC Directive 92/69 Method A10
Remarks The test material has been determined to be not highly flammable as it failed to ignite in the preliminary screening test.
TEST FACILITY SafePharm Laboratories Ltd (2005c)

Autoignition Temperature 329°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids
TEST FACILITY SafePharm Laboratories Ltd (2005f)

Explosive Properties Based on the chemical structure of the test material, the result for the explosive properties has been predicted negative.

METHOD Predicted using EC Directive 92/69/EEC A.14 Explosive Properties
TEST FACILITY SafePharm Laboratories Ltd (2005f)

Reactivity The notifier claimed that the notified chemical is expected to be stable under normal conditions of use

ADDITIONAL TEST

Oxidizing Properties Based on the chemical structure, the result of the oxidising properties has been predicted negative.

METHOD Predicted using EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids)
TEST FACILITY SafePharm Laboratories (2005f)

7. TOXICOLOGICAL INVESTIGATIONS

The following toxicity data were provided for assessment.

Endpoint and Result	*Assessment Conclusion*
1. Rat, acute oral	Low toxicity (LD0 > 2000 mg/kg bw)
2. Rabbit, skin irritation	Non-irritating
3. Rabbit, eye irritation	Non-irritating
4. Guinea pig, skin sensitisation - Maximization test	No evidence of sensitisation.
5. Genotoxicity – Ames Test	Non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Red 003

METHOD: OECD TG 401 Acute Oral Toxicity
EEC 84/449 – Annex V – Method B1 (1984) – 91/325 (1991)

Species/Strain: Rat/Sprague-Dawley

Vehicle: Olive oil

Remarks – Method: A preliminary study was conducted in 3 groups of 2 male and 2 female rats at dose levels of 500, 1000, and 2000 mg/kg, respectively. They were treated under the same conditions as those employed in the main study and were administered the test substance as 5-10% and 20% (W/V) suspension in olive oil.

In the main study, the test substance was administered once only as a 20% (W/V) suspension in olive oil and at the dose level of 2000 mg/kg by the oral route (gastric gavage) in 5 male and 5 female rats.

Observations include mortality, clinical signs, body weight and necropsy examination at the end of the study.

Neither the stability nor the absorption of the test substance were determined.

RESULTS: LD0* > 2000 mg/kg bw

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Preliminary study			
1	2 males and 2 females	500	0
2	2 males and 2 females	1000	0
3	2 males and 2 females	2000	0
Main study			
4	5 males and 5 females	2000	0

* As no deaths were observed at the dose level administered, the dose level that proves lethal for 50% animals (LD50) cannot be calculated, therefore, the results of the LD0 was expressed.

Remarks – Results

Signs of toxicity
There were no changes in behaviour or clinical signs in any of the treated animals during the observation period. Reddish stools were noted on Day 2 and 3 only, which is probably due to the colour of the test substance. Body weight changes in the treated animals were not influenced by treatment.

Effects in organs
There were no macroscopic findings that could be associated with

treatment.

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

TEST FACILITY Hazleton France (1992a)

7.2. Irritation – skin

TEST SUBSTANCE Red 003

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion
EEC 84/449 – Annex V – Method B4 (1984) – 91/325 (1991)

Species/Strain	Rabbit/New Zealand Hybrid Albino White males
Number of Animals	3
Vehicle	Olive oil
Observation Period	72 h
Type of Dressing	Semi-occlusive
Remarks – Method	The test substance was applied at the dose level of 0.5 g moistened with 0.65 g of olive oil per animal, under a semi-occlusive bandage for 4 hours, to the intact skin of rabbits. Examinations for erythema and oedema were performed 1, 24, 48 and 72 hours after removal of the bandage.

RESULTS

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

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

Remarks – Results An excess of the test substance was observed after removal of the semi-occlusive patch, and a wiping was performed with a gauze pad moistened with pure olive oil. The reading was carried out 1 hour later. The test substance had tinted the skin thus making observation of erythema imprecise.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Hazleton France (1992b)

7.3. Irritation – eye

TEST SUBSTANCE Red 003

METHOD OECD TG 405 Acute Eye Irritation/Corrosion
EEC 84/449 – Annex V – Method B5 (1984) – 91/325 (1991)

Species/Strain	Rabbit/New Zealand Hybrid Albino Male
Number of Animals	3
Observation Period	72 h
Remarks – Method	The test substance was administered as supplied without rinsing and at dose level of 30 mg (quantity corresponding to a volume of 0.1 ml) per animal, into the inferior conjunctival sac of the right eye of 3 male rabbits. Examinations in the conjunctiva, iris and cornea were performed 1, 24, 48 and 72 hours after administration of the test substance.

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	0	0	0	-	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0.33	0	0	1	24 h	0

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

Remarks – Results: Adherence to cornea in 2/3 animals at the 1 hour observation.

CONCLUSION: The notified chemical is non-irritating to the eye.

TEST FACILITY: Hazleton France (1992c)

7.4. Skin sensitisation

TEST SUBSTANCE: Red 003

METHOD: OECD TG 406 Skin Sensitisation – Guinea pig maximization test
EEC 84/449 – Annex V – Method B6 (1984) – 91/325 (1991)

Species/Strain: Guinea pig/Albino Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
Intradermal (Induction): 1.0% (w/w) suspension in sterile Codex liquid paraffin.

Topical (Induction): 45% (w/w) paste

Topical (Challenge): 45% (w/w) paste

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 20

Induction phase: Induction Concentration
Intradermal:
0.1 ml (1 injection) per area and per animal of the test substance in a 1.0% or 0.5% or 0.2% (w/w) suspension in sterile Codex liquid paraffin.

Topical:
Occlusive for 48 hours. 0.5 ml per area and per animal of the test substance as a 45% (w/w) paste or in a 22.5% (w/w) suspension in sterile Codex liquid paraffin.

Signs of Irritation: The test substance tinted the skin of the animals thus making erythema observation impossible. No oedema was noted.

CHALLENGE PHASE

1st challenge: Topical application:
Occlusive for 24 hours. 0.5 ml per area and per animal of the test substance in a 22.5% (w/w) suspension in sterile Codex liquid paraffin.

2nd challenge: No 2nd challenge test was conducted.

Remarks – Method: Macroscopic examinations of the skin were conducted to the challenge application sites 24 and 48 hours after removal of the patches.

As the test substance tinted the skin of the animals thus making erythema

observation impossible, histopathological examinations of the skin were preformed for all the animals of the treated and the control group (half of them at 24 hours and in the other half at 48 hours).

No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	22.5%	0/20	0/20	-	-
Control Group	22.5%	0/20	0/20	-	-

Remarks – Results

The macroscopic and histopathological examinations did not reveal any lesion of delayed hypersensitivity in the treated animals. A slight irritation was noted after histopathological examination in both the treated and the control animals.

Under the experimental conditions employed, the test substance did not provoke any reaction of cutaneous sensitisation in the animals examined.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY

Hazleton France (1992d)

7.5. Genotoxicity – bacteria

TEST SUBSTANCE

Red 003

METHOD

OECD TG 471 Bacterial Reverse Mutation Test
EEC 84/449 – annex V – Method B14 (1984)

Species/Strain

S. typhimurium:
TA1538, TA1535, TA1537, TA98, TA100

Metabolic Activation System

Liver fraction (S9 mix)

Concentration Range in Main Test

a) With metabolic activation: 0.1 - 5 mg/plate.
b) Without metabolic activation: 0.1 - 5 mg/plate.

Vehicle

DMSO

Remarks – Method

A preliminary study was performed on strain TA100 without metabolic activation at doses ranging from 0.1 to 5 mg/plate.

No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	NA	0.1 mg/plate (TA 1537)	NA	No
Test 2	NA	2.5mg/plate (TA 1537)	NA	No
Absent				
Test 1	> 5mg/plate	2.5 and 5mg/plate (TA98)	NA	No

Test 2	NA	> 5mg/plate	NA	No

NA, not applicable.

Remarks – Results

Preliminary study

No toxicity was observed for TA 100 bacterial strain at the concentration of 5 mg/plate.

Main Study

The positive control articles all induced large increase in revertants numbers in the appropriate strains with and without metabolic activation.

In the first study, some signs of cytotoxicity were observed for TA 98 bacterial strain at the concentrations of 2.5 and 5 mg/plate tested without activation.

For all tested concentrations, the mean number of colonies was less than twice the mean number of colonies in the negative control excepted for TA 1537 bacterial strain with metabolic activation:

- at the concentration of 0.1 mg/plate in the first study
- at the concentration of 2.5 mg/plate in the second study

These slight increases in colony number were observed at two different test substance concentrations in 2 identical assays. In addition, individual values were within the normal range and there was no increase in number of colonies with increasing dose in either assay. Thus, these small differences were not considered to represent a mutagenic response.

CONCLUSION

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

TEST FACILITY

Hazleton France (1992e)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Red 003

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.

EC Directive 92/69/EEC C.4-C Biodegradation: Determination of the " Ready" Biodegradability: Carbon Dioxide Evolution Test

Inoculum	Activated sewage sludge microorganisms
Exposure Period	28 days
Auxiliary Solvent	Sodium benzoate
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks – Method	No deviations from standard protocol. The test material was dispersed in the culture medium with the aid of high sheer mixing.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*
0	0	0	0
1	2	1	33
3	2	3	79
6	1	6	81
10	8	10	94
16	6	16	94
22	4	22	110
27	4	27	118
28	5	28	119
29*	6	29*	117

* Day 29 values corrected to include any carry-over of CO2 detected in Absorber 2

Remarks – Results: The test material attained 5% degradation after 28 days and therefore cannot be considered to be readily biodegradable. The control results indicate that the inoculum was suitable, and validates the test.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY: SafePharm Laboratories (2005d)

8.1.2. Bioaccumulation

The notified chemical has very low water solubility and, therefore, the potential for bioaccumulation exists. However, given the highly diffuse release and very low aquatic exposure, this is not expected to be significant.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE: Red 003

METHOD: OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Limit test

EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia –

	Immobilisation test
Species	*Daphnia magna*
Exposure Period	48 hours [acute study]
Auxiliary Solvent	
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	WAF
Remarks – Method	250 mg of test material was added to the surface of 2.5 L reconstituted water. After stirring for 23 hours, the mixture was allowed to stand for 1 hour. Microscopic examination of the WAF showed particles of test material dispersed throughout and therefore the WAF was removed by filtering through 10 µm filter paper. After filtration, microscopic examination showed no micro-dispersions or undissolved test material to be present, however, visual observation showed the WAF to be a pale red dispersion throughout the test. The analytical results, taken at 0 and 48 h, indicate very little (<0.6 mg/L) had dissolved.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*		
Nominal	*Actual*		*3 h*	*24 h*	*48 h*
Control		20	0	0	0
100	0.177-0.567	20	0	0	0

EL50	>100 mg/L WAF at 48 hours
NOEC	100 mg/L WAF at 48 hours
Remarks – Results	A positive control using potassium dichromate as the reference material confirmed the suitability of the test organisms.

CONCLUSION The notified chemical is not toxic to *Daphnia magna*, up to the limits of its water solubility.

TEST FACILITY SafePharm Laboratories (2005e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is expected that approximately 10% of the total imported volume (1,000 kg) of notified chemical will be disposed of by incineration, resulting in thermal decomposition to simple oxides of carbon, nitrogen and chlorine. In typical situations. a further 30-60% of the total imported volume of notified chemical would be expected to be disposed of to landfill, with the remainder be released to the aquatic environment. However, given the very low water solubility of the notified chemical, it is reasonable to expect that a greater proportion (up to 80%) will be disposed of to landfill, directly or indirectly after removal from sewage treatment plants. In landfill, the notified chemical is expected to slowly degrade via biotic and abiotic processes to form simple compounds.

Since only a small proportion (10%) of the chemical is expected to pass through sewage treatment plants, under a worst case scenario, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis, Predicted No-Effect Concentration (PNEC) and Risk Assessment (Q) are estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Annual quantity of chemical released to sewer	100	kg/year
Days per year where release occurs	260	days/year

Daily chemical release	0.38	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.09	µg/L
PEC - Ocean:	0.01	µg/L

9.1.2. Environment – effects assessment

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates)	>0.18	mg/L*
Assessment Factor	1,000.00	
PNEC:	>0.18	µg/L

* Based on amount dissolved.

9.1.3. Environment – risk characterisation

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.09	>0.177	<0.530
Q - Ocean:	0.01	>0.177	<0.053

As the PEC/PNEC ratio is less than 1 for both river and ocean, there should be an acceptable risk to aquatic organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported at <1% an ink 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.

Office workers may be exposed to the notified chemical while changing spent cartridges or during normal printing processes and service technicians while removing cartridges, repairing and cleaning, primarily through dermal contact. Ocular and inhalation exposure are not expected due to sealed cartridges and low volatility of the notified chemical. Service technicians are expected to have the highest potential occupational exposure. However, due to the design of the cartridge, dermal exposure for all workers is likely to occur only occasionally and to small quantities of the notified chemical at a concentration of < 1%. Therefore, dermal exposure is expected to be low. Exposure will be minimised by the use of disposable gloves by service personnel.

Exposure to the notified chemical on printed-paper is low as the ink is bound to the paper matrix. Some intermittent exposure may occur if printing onto a non-absorbent substrate occurs and the ink does not dry in a short time.

9.2.2. Public health – exposure assessment

Exposure of the public to the notified chemical is expected to be low due to the small quantity of notified chemical in each cartridge, sealed cartridge, and the controlled release during printing.

9.2.3. Human health – effects assessment

Toxicological data for the notified chemical was submitted for acute oral, skin and eye irritation, skin sensitisation and mutagenicity.

The acute oral study in rats indicated low acute toxicity (>2000mg/kg bw).

The skin and eye irritation studies in rabbits showed that the notified chemical is not irritant.
The notified chemical did not demonstrate a sensitisation property in animals.
A reverse mutation test in *Salmonella typhimurium* (with and without activation) indicated the notified chemical was not mutagenic to bacteria.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

9.2.4. Occupational health and safety – risk characterisation

The risk of adverse effects to workers is considered to be low due to the low concentration of the notified chemical as introduced (< 1% notified chemical), limited exposure to the notified chemical expected during usual conditions of use in the office environment, and the low toxicity of the notified chemicals.

9.2.5. Public health – risk characterisation

Due to the low exposure expected and low health concern, the risk of adverse effects to the public is considered to be negligible.

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

The chemical is not considered to pose a risk to the environment based on its reported volume and 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 in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of an ink product containing the notified chemical provided by the notifier was assessed in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The following amendments are recommended for MSDS for ink:

- Statement of Hazardous Nature; and
- Emergency Telephone Number in Australia.

11.2. Label

The label for an ink product 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, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls or work practices are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.
- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing printer cartridges containing the notified chemical and during routine maintenance and repairs.
- 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 by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

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; and
- the importation volume exceeds one tonne per annum notified chemical.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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