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May 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

FJC-001H

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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett-Packard Australia Ltd (ABN 25 084 864 479)
31-41 JOSEPH STREET
BLACKBURN, VICTORIA 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:
Chemical Name
Other Names
CAS Number
Molecular and Structural Formulae
Molecular Weight
Spectral Data
Purity,
Hazardous and Non-hazardous Impurities
Additives/Adjuvants
Use Details
Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a function of pH
Dissociation constant
Flash point
Boiling point
Oxidizing properties
Acute inhalation study

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
UK (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FJC-001H

3. COMPOSITION

DEGREE OF PURITY
>90%

4. INTRODUCTION AND USE INFORMATION

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

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 is a component of a water-soluble ink for use in ink-jet printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Hewlett-Packard Australia Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported from Japan in sealed ink cartridges. The cartridges will be packed in sturdy cardboard boxes and normally be transported and distributed to customers by road.

5.2. Operation description
No reformulation or repackaging of the notified chemical occurs in Australia. The sealed ink jet cartridge containing the notified chemical will be delivered to the commercial and public users in its original packaging. The ink jet cartridge will be handled by service technicians and office workers and the public when replacing spent cartridges in the printer.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Retail/office workers	10	4 hours/day	70 days / year
Storage/transport workers	100	6 hours / day	240 days /year
Service Engineers/office workers	1000	<0.1 hours / day	intermittent

Exposure Details
Exposure to the notified chemical during the importation, transport and storage of the printer cartridges is not expected except in the unlikely event of an accident where the sealed cartridge and its packaging may be breached. The cartridges will be distributed to a number of outlets, the cardboard cartons opened and individual boxes stacked on shelves.

Office workers and customer service engineers may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, and during repair, maintenance and cleaning of ink jet printers. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Customer service engineers often 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 of office workers may occur upon handling printed matter. However, very little printing ink is used per sheet of paper and it would not be available for exposure or dermal uptake as it is fused and fixed to the printed surface, except on rare occasions where the ink has not completely dried or is printed to non-absorbent substrate.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Printer ink will be imported in ready-to-use cartridges (containing <10% notified chemical). No release is expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and will not open during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. Installation and replacement will be contained with absorbent and disposed of in landfill. Cartridges are contained within the printer until the contents are used then they are removed and sent to a recycling and disposal centre.

Most of the notified chemical (>98%) will be bound to the printed paper, which will be disposed of to landfill, recycled or incinerated. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The waste is expected to go to trade waste sewers. Approximately 50% of the ink printed on paper will enter paper recycling of which a proportion of the ink is expected to be recovered during recycling. While most may partition to water, due to the low percentage of the notified chemical in these inks and the widespread use, release to the aquatic compartment from any given recycling plant will still be low based on worst case assumptions. Any chemical absorbed to sludge during recycling process will be disposed of to landfill.

5.5. Disposal

The total import volume of the notified chemical will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified chemical bound to the paper. Some will enter the paper recycling process. Used cartridges will be sent to recycling and disposal centres. The cartridges will be broken down into component parts for recycling. Residual ink (< 2% of the notified chemical) left in the empty cartridges will be separated from the cartridges and incinerated during the recycling of the cartridges.

Notified chemical that is incinerated is expected to thermally decompose to form predominantly simple organic compounds and various salts. Similarly, notified chemical that is disposed of to landfill should eventually degrade.

5.6. Public exposure

The printing ink will be available for use in home printers. Therefore, the public may have dermal exposure to printing ink containing <10 % of the notified chemical when inserting or removing a damaged cartridge and clearing paper jams and/or from residues in the printer. However, exposure would be minimal as the ink is contained in the cartridge and the physical design of the cartridge prevents handlers from dermal exposure. The cartridge design also prevents leakage of ink. Public exposure is also possible from handling printed pages prior to the ink being fully dried or if a non-absorbent substrate is placed in the printer.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Dark blue crystalline solid
Melting Point/Freezing Point	Decomposes at 335 ºC

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature
Remarks	The chemical decomposes prior to melting.
TEST FACILITY	SPL (2003a)

Boiling Point Not determined

Remarks Test not conducted as the notified chemical decomposes prior to melting at 335 °C.

Density 1610 kg/m^3 at 21 °C

METHOD EC Directive 92/69/EEC A.3 Relative Density
TEST FACILITY SPL (2003b)

Vapour Pressure 4.1 x10^{-8} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure
Remarks Measurements were done at several temperatures and linear regression analysis was used to calculate the vapor pressure at 25 °C.
TEST FACILITY SPL (2003c)

Water Solubility 270-28l g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask method was used, however, no analysis could be performed due to the high solubility of the notified chemical producing unfilterable mixtures and thus the water solubility was estimated based on visual inspection.
TEST FACILITY SPL (2003a)

Hydrolysis as a Function of pH Not determined

Remarks While one potentially hydrolysable group is present, the test material contains complex components; as such the monitoring of these components would be extremely difficult.

Partition Coefficient (n-octanol/water) log P_{OW} at 20°C = -3.91

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Test was performed using a shake-flask method at pH 7 with analysis by HPLC.
TEST FACILITY SPL (2003a)

Adsorption/Desorption log K_{OC} <1.25

METHOD EC Directive 2001/59/EC C.19 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography
Remarks Test was performed using the HPLC screening method at pH 7. The notified chemical eluted before the standard solution of acetanilide, indicating it is highly mobile in soil or sediment.
TEST FACILITY SPL (2003b)

Dissociation Constant Not determined

Remarks The notified chemical is a salt of a strong acid, which is expected to remain dissociated under all environmental pH conditions.

Particle Size

METHOD Data acquired using a procedure (sieve method) designed to comply with European Commission technical guidance document 'Particle Size Distribution, Fibre Length and Diameter Distribution' (June 1996), which satisfies the requirements of OECD Guideline 110.

Range (µm)	*Mass (%)*
< 100	6.9

Remarks The test results indicate that the solid test material can be considered as essentially non-inhalable.
TEST FACILITY SPL (2003b)

Flash Point Not applicable

Remarks Solid at room temperature

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Test material failed to ignite in the preliminary screening test.
TEST FACILITY SPL (2003d)

Autoignition Temperature 331 °C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY SPL (2003c)

Explosive Properties Prediction model used

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks There are no chemical groups that would imply explosive properties.
TEST FACILITY SPL (2003c)

Reactivity Expected to be stabile under the described use conditions.

Remarks The chemical is considered to be stable. There are no known hazardous decomposition products. However, the chemical is combustible and will burn if involved in a fire, evolving noxious fumes such as CO_2, CO, SO_2, NO_x.

Surface Tension 71.9 mN/m at 19 °C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension result was not corrected using the Harkins-Jordan correction table as the correction was not considered applicable to the apparatus used. Once calibrated, the balance and ring assembly used in the test give a direct reading for surface tension that is within the required accuracy (±0.5 mN/m). This deviation has been considered not to have affected the integrity of the study.
TEST FACILITY SPL (2003b)

Oxidizing Properties

METHOD Predicted using method A.17 EC of Directive 92/69/EEC Oxidizing Properties (Solids).
Remarks There are no chemical groups that would imply oxidizing properties.
TEST FACILITY SPL (2003c)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating with irreversible colouration of the conjunctival membranes
Guinea pig, skin sensitisation – LLNA test.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL >1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chinese Hamster Lung fibroblasts	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley CD
- Vehicle: Distilled water
- Remarks - Method: No significant variations of the method were reported

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 female	2000	0/3
2	3 female	2000	0/3

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Blue-colored diarrhea and stain on bedding were observed in Group 1 females 2 to 4 hours after dosing. Blue-stained faeces were observed in all treated animals 1 to 3 days after dosing.
- Effects in Organs: Group 2 females had dark kidneys at necropsy. No abnormalities were seen on Group 1 females at necropsy.
- Remarks - Results: No mortality occurred. All animals appeared normal three or four days after dosing, and showed expected body weight gains over the study period.

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

TEST FACILITY — SPL (2003e)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
- Species/Strain: Rat/Sprague-Dawley CD
- Vehicle: Moistened with distilled water
- Type of dressing: Semi-occlusive.
- Remarks - Method: After the 24h contact period, residual test material was wiped from the skin with cotton wool moistened with distilled water.

RESULTS

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

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Very slight erythema was noted on all treated skin sites one and two days after treatment. Two treated skin sites had erythema for three days and one had erythema, which persisted for up to five days after treatment.
Signs of Toxicity - Systemic	None
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	No mortality was observed during the study. Blue-coloured staining was noted on all treated skin sites but the staining did not preclude the evaluation of erythema.

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

TEST FACILITY — SPL (2003f)

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	Moistened with distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	After the application period, residual test material was wiped from the skin by gentile swabbing with cotton wool soaked in industrial methylated spirits.

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	n/a	0
Oedema	0	0	0	0	n/a	0

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

Remarks - Results — No evidence of skin irritation was noted.

CONCLUSION — The notified chemical is non-irritating to the skin.

TEST FACILITY — SPL (2003g)

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 male
Observation Period	21 days

Remarks - Method: Initially a single animal was tested to evaluate possible ocular effects. After consideration of the ocular responses, two additional animals were tested.

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	0.67	0.67	2	48h	0
Conjunctiva: chemosis	0	0.33	0.33	1	24h	0
Conjunctiva: discharge	0	0.33	0.33	2	24h	0
Corneal opacity	0	0	0	0	n/a	0
Iridial inflammation	0	0	0	0	n/a	0

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

Remarks - Results: No effect on the cornea or iris was observed. Two treated eyes had moderate redness of the conjunctiva at 1 hour, which was slight by 24 and 48 hours. Slight chemosis and moderate discharge was observed, which resolved by 48 hours.

Blue coloured residual material was noted around the treated eyes of 2 animals, which persisted up to 48 hours in one animal.

Blue coloured staining of the conjunctival membranes and fur around the treated eyes were noted in all treated animals throughout the study.

CONCLUSION: The notified chemical is slightly irritating to the eyes but causes irreversible colouration of the eyes.

TEST FACILITY: SPL (2003h)

7.12T. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 429 Skin Sensitisation - mouse local lymph node assay (LLNA)

Species/Strain: Mouse/CBA/CaBkl

Vehicle: 0.5% Tween 80 in distilled water

Remarks - Method: No significant protocol deviation

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1214	1
0.1	946	0.78
1	633	0.52
10	766	0.63
Positive Control- α-hexylcinnamaldehyde		
5	Not reported	5.7
10	Not reported	5.5
50	Not reported	33.5

Remarks - Results: No deaths occurred. No signs of systemic toxicity were noted during the study.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	SPL (2003i)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Japanese Chemical Substances Law (2000) Guidance of Japanese Chemical substances Control Law (1986)
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 5/7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	Method used was analogous to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. Stability of the test substance was confirmed by analysis. Dosage levels were chosen from a range finding study. Histopathology performed on high dose and control animals only.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	100	0
III (mid dose)	5/sex	300	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

No mortalities were observed in any of the group of animals.

Clinical Observations

There were no clinical effects observed during the study. No abnormalities were seen in the detailed observations of general condition, food intake and functional examinations.

Blue coloration was seen in urine and faeces of all treated animals. The coloration of the faeces was reversible at the end of the recovery period. The coloration of the urine was reversible 24 h after dosing.

Females of the high dose group showed increased body weight gain compared with the control group but this was considered to be incidental.

No significant behavioral changes were observed in any of the groups of animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Prolonged activated partial prothrombin time (APTT) in high dose females compared with control group was observed. In the high dose recovery group, decreased platelet count was observed.

Decreased blood urea nitrogen (BUN) level and total protein in high dose males compared with control group.

Decreased albumin/globulin ratio was observed in the high dose recovery group.

Urinalysis

No abnormalities apart from the blue colouration of urine were seen which was reversible within 24 hours of dosing.

Effects in Organs

No changes were seen in the organ weights.
At necropsy, intestinal contents below the ileum showed blue discolouration without any morphological changes. In the recovery group, the colour of the alimentary tract contents was normal at necropsy.
Microscopic findings
Small granulation foci in the liver and eosinophilic bodies in the proximal tubular epithelium of the kidneys were seen in both, high dose and control groups. At necropsy, the renal cortex of treated animals showed blue colouration without any histopathological changes.

Remarks – Results

In the haematology of the recovery group low platelet levels and low A/G ratio were observed. However, these changes were minimal and considered to be within the normal variation.
In addition, blue staining similar to the test material was seen in the faeces and urine as well as alimentary tract contents and renal cortex at necropsy. However no physiological toxic effects could be associated with this staining.

CONCLUSION

The No Observed Effect Level (NOEL) was established as > 1000 mg/kg bw/day in this study, based on the absence of any significant treatment related effect in animals treated with up to 1000 mg/kg bw/day of notified chemical.

TEST FACILITY Saitama Laboratory (2002)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD

	OECD TG 471 Bacterial Reverse Mutation Test.
	Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver.
Concentration Range in	a) With metabolic activation: 0 - 5000 µg/plate.
Main Test	b) Without metabolic activation: 0 - 5000 µg/plate.
Vehicle	Sterile distilled water
Remarks - Method	Dose levels were adjusted to take into account purity.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	Negative
Test 2	>5000	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2	>5000	>5000	>5000	Negative

Remarks - Results No significant increases in the number of revertant colonies were observed in any strain at any dose level. 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 Material Safety Test Center (2002a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chiness Hamster
Cell Type/Cell Line	Lung Fibroblasts (CHL/IU)
Metabolic Activation System	S9 mix from Phenobarbital and 5,6-benzoflavone induced rat liver
Vehicle	Sterilized saline
Remarks - Method	Preliminary cell growth inhibition test, which was conducted at a dose range of 0.0098 to 5.0 mg/mL, demonstrated that the approximate 50% cell growth inhibition dose was > 5 mg/mL (the highest dose tested) for both the short and continuous treatment regimes. In the absence of metabolic activation system, 0.025 and 0.05 µg/ml Mitomycin C was used as a positive control. In the presence of metabolic activation system, 0.02 mg/ml Benzopyrene was used as a positive control.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	160; 310; 630; 1300*; 2500*; 5000*	6h	24h
Test 2	160; 310; 630; 1300*; 2500*; 5000*	24h	24h
Test 3	160; 310; 630; 1300*; 2500*; 5000*	48h	48h
Present			
Test 1	160; 310; 630; 1300*; 2500*; 5000*	6h	24h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	not observed	negative
Test 2	> 5000	> 5000	not observed	negative
Test 3	> 5000	> 5000	not observed	negative
Present				
Test 1	> 5000	> 5000	not observed	negative

Remarks - Results	No significant increase in the percentage of cells with chromosomal aberrations was observed in the absence or presence of metabolic activation in any of the type of treatments. Also, no precipitation of the notified chemical was seen. The satisfactory performance of the study was indicated by the expected frequency of the cells with structural aberrations in the negative and positive control tests.
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster Lung fibroblasts treated in vitro under the conditions of the test.
TEST FACILITY	Material Safety Test Center (2002b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Standard activated sludge
Exposure Period	14 days
Auxiliary Solvent	Nil
Analytical Monitoring	BOD / HPLC / TOC
Remarks – Method	Measurement of Biological Oxygen Demand was conducted using a closed-system oxygen consumption meter (Kitakaishi type coulometer). Aniline was used as a control.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
7	0	7	69
14	0	14	70

Remarks – Results	As a result of the biodegradability study, the percentage degradation calculated from BOD was 0% on average. The percentage degradation calculated from HPLC analysis was 1% on average, and the percentage degradation calculated from TOC analysis was 1% on average.
CONCLUSION	The test material is not considered to be biodegradable under the conditions of this study.
TEST FACILITY	SPL (2003j)

8.1.2. Bioaccumulation

Remarks – Results	A bioaccumulation study was not conducted. As the Log Pow is very low (-3.91) the potential for bioaccumulation is very low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test–semi static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi static
Species	Rainbow trout (*Oncorhynchus mykiss*) [juvenile]
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Chemical analysis at 0, 24, 48, 72 and 96 hours
Remarks – Method	A range-finding test was conducted at 1.0, 10 and 100 mg/L. Based on the results for the range-finding test a Limit test using 3 fish per concentration was conducted at a concentration of 100 mg/L to confirm that at the maximum concentration given in the OECD/EEC Test Guidelines no mortality or sub-lethal effects of exposure were observed. 20 L glass exposure vessels were used and the photoperiod was 16 h light: 8 h dark with transition periods. Fish were acclimatised 7 days prior to testing, and no mortality was recorded prior to the tests. Analytical testing showed that the test material was stable during the tests (85-113% of nominal) and thus nominal concentrations were used. Temperature: 12.0-13.8°C. pH 7.5-8.3. Dissolved oxygen 7.5-8.6 mg/L. Concentration of standards and test solutions were determined spectrophotometrically using an external standard.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0	0
100R1	-	10	0	0	0	0	0
100R2	-	10	0	0	0	0	0

R1 and R2 = Replicates 1 and 2

LC50	>100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	The results of the definitive study showed that no mortalities were observed in the test vessels with 100 mg/L of test substance in both replicates for the duration of the tests. The very dark blue solutions were clear throughout and there were no sub-lethal effects of exposure observed in the 20 fish exposed to a test concentration of 100 mg/L for a period of 96 hours. It was considered unnecessary and unrealistic to test at concentrations in excess of 100 mg/L.
CONCLUSION	The notified chemical was found to be not harmful to rainbow trout up to a concentration of 100 mg/L.
TEST FACILITY	SPL (2003k)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Range-finding and definitive tests were performed. At concentrations of 0.010, 0.10, 1.0 and 100 mg/L, no immobilisation was observed. Test concentrations (definitive test) of 1.8, 3.2, 5.6, 10, 18, 32, 56, 100 and 180 mg/L were employed. Photoperiod: 16 h light: 8 h dark with transition periods. Standards and test solutions were tested by HPLC. Test pH 7.9-8.0. Temperature 20.7-20.9°C. Dissolved oxygen 8.2-8.4 mg/L. Analytical monitoring at 0 and 48 hours showed measured test concentrations to range from 99% to 112% of nominal and so the results are based on nominal concentrations only.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<LOQ	20	0	0
1.8	1.93-2.02	20	0	0
3.2		20	0	0
5.6	5.71-5.79	20	0	0
10		20	0	0
18	17.9-18.3	20	0	1
32		20	0	1
56	56.3-57.3	20	3	4
100		20	3	5
180	185-188	20	4	7

LC50	>180 mg/L at 48 hours
NOEC	10 mg/L at 48 hours
Remarks – Results	In the definitive study, no effects were observed in the test vessels with less than 32 and 10 mg/L of test substance for periods of 24 and 48 hours respectively. These were blue solutions of increasing intensity with increasing concentration. After 48 h, 35 % immobilisation was observed at a test concentration of 180 mg/L, so an EC50 could not be calculated. It was considered unnecessary to test at concentrations above 180 mg/L in another test as the recommended test concentration in the Test Guideline is 100 mg/L at which 25% immobilisation was observed in the definitive test.
CONCLUSION	The notified chemical was found to be not harmful to *Daphnia magna*.
TEST FACILITY	SPL (2003l)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green algae *Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	1.0, 3.2, 10, 32, 100 mg/L
Concentration Range Actual	90-100%
Auxiliary Solvent	None
Water Hardness	Not given
Analytical Monitoring	Standards and test solutions were tested by UV-visible spectroscopy. These were 90-108% of nominal at test initiation and declined slightly by 72 h. Samples of the algal populations were measured for each control, group and treatment using Coulter® Multisizer II particle Counter.
Remarks – Method	Duplicate experiments (A and B) were performed to differentiate growth effects between toxicity and reduced light causes. Experiment A: Algae were exposed to test material in a flask enclosed from above by a petri dish containing culture medium only. Inhibition was due to a combination of toxicity and reduction in light intensity. In Experiment B, algae were not exposed to the test material in the flasks, but the flasks were enclosed by petri dishes containing the culture media and the test material. Therefore, inhibition of algal growth was due to a reduction in light intensity alone. The difference between Experiments A and B inhibition values is presumed to be due to the toxic effect of the test material on algal cells. Mean cell density in Expt. A was $1.03X10^4$ cells/mL (initial) and $2.41X10^5$ cells/mL (72 hours). Mean cell density in Expt. B was $1.08X10^4$ cells/mL (initial) and $2.33X10^5$ cells/mL (72 hours). Constant illumination and stirring. Temperature 24±1 °C. pH 7.4-7.6.

RESULTS

	Biomass		*Growth*	
	EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
Expt A:	9.4 mg/L	1.0 mg/L	39.0 mg/L	1.0 mg/L
Expt B:	14.0 mg/L	1.0 mg/L	46.0 mg/L	1.0 mg/L

Remarks – Results	Given that significant differences (greater than 10%) in the inhibition values between Experiments A and B were observed, it was considered that the effect of the test material on algal growth was not only due to a reduction in light intensity, but also due to the intrinsic toxic properties of the test material. Therefore, for classification purposes the results determined from Experiment A should be used.
CONCLUSION	The results indicated the combined toxic nature of the test material and the reduction in light intensity. The test material is toxic to algae.
TEST FACILITY	SPL (2003m)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sewage
Exposure Period	3 hours
Concentration Range Nominal	10-1000 mg/L
Remarks – Method	Following a preliminary range-finding test using test concentrations of 1.0, 10, 100 and 1000 mg/L, activated sludge was exposed in the definitive test to an aqueous solution of the test material at the test concentration of 1000 mg/L in a "limit test" for a period of 3 hours at 21°C with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.
RESULTS	
IC50	>1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The validation criteria for the control respiration rates and reference material EC50 values have been satisfied. It was considered unnecessary and unrealistic to test at concentrations in excess of 1000 mg/L.
CONCLUSION	The effect of the test material on the respiration of activated sludge micro-organisms gave a 3-hour EC50 of greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L. The validation criteria for the control respiration rates and reference material EC50 values were satisfied, thus validating the test.
TEST FACILITY	SPL (2003n)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Manufacture, reformulation and packaging into end-use containers occurs overseas, and release is not expected. After use, printed paper may be disposed of by incineration, to landfill or be recycled. Notified chemical disposed of to landfill, may be mobile, however, the low proposed annual import volume, and diffuse release throughout Australia will mitigate any potential exposure while the notified chemical slowly degrades.

In Australia, approximately 50% of printed paper is recycled. The following Predicted Environmental Concentration calculation assumes this 50% recycling, and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50.000%	
Annual quantity of chemical released to sewer	500.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.37	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.33	µg/L
PEC - Ocean:	0.03	µg/L

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data were provided for three trophic levels, with algae demonstrating the highest level of sensitivity to the notified chemical. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Alga).	39.00	mg/L
Assessment Factor	100.00	
Mitigation Factor	1.00	
PNEC:	390.00	µg/L

9.1.3. Environment – risk characterisation

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.33	390	0.001
Q - Ocean:	0.03	390	0.000

This indicates that the current import volume and use pattern is not expected to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed sealed cartridges at concentration <10%. Transportation, storage, and office workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

Office staff and service engineers may be exposed to the notified chemical contained in cartridges via skin contact when replacing spent cartridges, cleaning paper jams or during maintenance and servicing. However, the service engineers will wear appropriate gloves and receive appropriate training in servicing techniques. Therefore, there is low potential for workers to be exposed to the notified chemical when replacing spent cartridges and adding new print heads to printers. The ink is released from a cartridge or print head by an electronic signal from the printer to the print head or cartridge. The electronic signal only occurs during the printing process and not during the replacement of print heads or cartridges. This reduces the potential for exposure during maintenance. Printers are equipped with filters and other barriers to prevent exposure during printing.

Contact with paper printed with ink containing the notified chemical unlikely to result in dermal exposure as the chemical will be bound within the matrix of the paper and become inert, except if the paper or other substrate is handled before the ink has dried.

9.2.2. Public health – exposure assessment

The printing ink will be available for use in home printers. Therefore, the public may have dermal exposure to <10 % of the notified chemical in the printing ink when inserting or removing a damaged cartridge and clearing paper jams and/or from residues in the printer. However, exposure would be minimal as the ink is contained in the cartridge and the physical design of the cartridge prevents handlers from dermal exposure. The cartridge design also prevents leakage of ink.

Public exposure is also possible from handling printed pages prior to the ink being fully dried or if a non-absorbent substrate is placed in the printer. When used as directed, the ink deposited on the printed pages is bound to the paper and hence not biologically available it is once dried, thus minimizing exposure to the notified chemical.

The use of the cartridges by the public is likely to be less frequent than the use by office workers.

9.2.3. Human health – effects assessment

Acute toxicity

The notified chemical shows low acute oral and dermal toxicity. In both cases LD50 was greater than 2000 mg/kg bw

Irritation and Sensitisation

The notified chemical is not irritating to the skin and causes only slight irritation to the eyes. However, it causes irreversible colouration of the conjunctival membranes of the eyes warranting Hazard classification R 41 - Risk of serious damage to eyes.

Repeated Dose Toxicity (sub acute, sub chronic, chronic)

Repeat oral administration of the notified chemical for 28 days did not cause any significant adverse effects at doses up to 1000 mg/kg bw/day. When applied orally under the condition of repeat dosing, coloration of the urine and faeces was observed that was reversible and without any physiological disturbances. Therefore the NOEL for repeat exposure to the notified chemical could be established at > 1000 mg/kg bw/day.

Mutagenicity

The notified chemical was not mutagenic in bacterial test systems and was negative in a chromosomal aberrations test with mammalian cells in vitro. Thus, the notified chemical is not likely to be mutagenic in humans.

Hazard classification for health effects.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

Xi

R41 - Risk of serious damage to eyes

9.2.4. Occupational health and safety – risk characterisation

Based on the available toxicological data, the notified chemical can cause slight irritation and irreversible colouration of the eyes. However, the risk of eye irritancy is low given the packaging and the low volume of the ink cartridges. Also, workers are adequately trained and wear disposable gloves to minimize the skin exposure and are advised to avoid eye and skin contact with the ink and observe general hygiene practices such as washing of hands after handling the cartridges.
The notified substance is neither a skin irritant nor a skin sensitizer and contact with the skin is low when used appropriately. Although inhalation exposure to the ink is unlikely, office printers should be positioned in well-ventilated areas.
Exposure through spillages is unlikely because of the fully enclosed ink cartridges. Personnel involved in cleaning-up of spills should protect themselves against respiratory, skin and eye exposure by wearing safety goggles together with appropriate gloves and overalls.
Overall the risk of exposure to the notified chemical to workers is low if used as directed.

9.2.5. Public health – risk characterisation

Considering the physico-chemical and toxicological properties of the notified chemical, the relatively low proportion in the ink (<10%), the pattern use and the type of packaging of the ink cartridge that minimizes and virtually eliminates possible exposure to the public, the notified chemical is unlikely to pose a significant risk to public. However, considering the potential of the notified chemical to cause eye damage through coloration in case of accidental exposure, the products available to the public should contain appropriate directions for use.
If used as directed the risk of exposure to the notified chemical to members of the public is 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:
Xi
R41 - Risk of serious damage to eyes

and

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*
Eye irritation/irreversible effects	1	Causes serious eye damage

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 described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 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.

11.2. Label

The label for the products 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:

  – Xi: R41 - Risk of serious damage to eyes

  – S24/25 Avoid contact with skin and eyes
  – S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  – S37 Wear suitable gloves
  – S39 Wear eye/face protection

- Use the following risk phrases for products/mixtures containing the notified chemical:

  – Conc ≥ 10%: R41
  – 5% ≤ concentration < 10%: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as used in printing inks:
  – Avoid contact with skin and eyes
  – Printers should be located in well-ventilated areas;

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as used in printing inks:
  – Appropriate goggles and 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
Disposal

- The notified chemical should be disposed of by 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(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.

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