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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Black Dye 1

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett-Packard Australia Pty Ltd of 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: chemical identity, impurities, spectral data, percentage of dye in ink product, the exact import volume, product details and manufacturer details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: flash point, particle size, dissociation constant and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None for the notified chemical.

NOTIFICATION IN OTHER COUNTRIES
EU, US and Switzerland.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Black Dye 1

3. COMPOSITION

DEGREE OF PURITY
High.

4. INTRODUCTION AND USE INFORMATION

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

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

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

USE
As a dye in cartridges for inkjet printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Hewlett Packard, Victoria 3130.

TRANSPORTATION AND PACKAGING
Products containing the notified chemical will be imported by ship in containers. Cartridges are packed in sturdy cardboard boxes and would normally be transported by road in Australia.

5.2. Operation Description

No reformulation or repackaging of the product containing the notified chemical occurs in Australia. Service technicians and office workers will handle the sealed ink-jet cartridge when replacing spent cartridges in printers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Service technicians	Approx 10	8 h/day (approx.)	230 days/year (approx.)
Office workers	Approx 1000	5-10 minutes/operation	Approx. 10 days/year

Exposure Details
Printing inks containing the notified chemical will be imported in pre-packed cartridges, each containing a low concentration of the notified chemical.

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

Office workers and printer maintenance workers may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, repairing or maintaining printers. Pre-packed ink cartridges are sealed and exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer. Maintenance workers may potentially come in contact with the notified chemical more often than office workers. Occupational exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Printer maintenance personnel usually wear cotton disposable gloves.

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

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release is expected as reformulation of the ink containing 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 as ink cartridges are designed to prevent leakage. These will be changed by office workers and the public. However, if leakage or spill does occur, the ink will be contained with absorbent material which will presumably be disposed of in landfill.

Ultimately, practically all the notified chemical will be released to the environment. Paper to which the notified chemical will be bound will eventually be buried in landfill or incinerated, or the chemical may be released in effluent from de-inking processes. Residues left in empty cartridges (estimated as <10% of ink) will most likely be disposed of to landfill.

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 wastes are expected to go to trade waste sewers. The notifier estimated that about 20% of the ink printed on paper will enter paper recycling and up to 60% of the ink is recovered during recycling. Together with the low percentage of notified chemical in the ink, release to the aquatic compartment will be in a highly diffuse manner.

5.5. Disposal

The disposal of uncured inks will be largely confined to residues contained in the cartridge systems that do not allow the replacement of individual colours. These residues are expected to remain in the cartridge housing and be disposed of by landfill.

5.6. Public exposure

The imported inkjet cartridges may be transported by air, ship, rail, or truck to their distribution location. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. The design also prevents leakage of ink. The public may be exposed to the notified chemical in the event of an accident during transport involving extensive breakage of cartridges.

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

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

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Black crystalline solid

Melting Point Not observed

METHOD	EC Directive 92/69/EEC A.1 Melting.
Remarks	Decomposes above 230°C
TEST FACILITY	Notox (1996a).

Density 1710 kg/m^3 at 20°C

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	The density was determined by a gas comparison pycnometer at 20°C
TEST FACILITY	Notox (1995a).

Vapour Pressure 0.0268 kPa at 20°C.

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Static vapour pressure measurements were made with a capacitance monometer. The samples vessel was filled with approximately 2.3 g of the test substance. The measurement was started at approximately 36°C and lowered to 23.30°C after measurement 26. The vapour pressure at 20°C was determined by fitting data from the vapour pressure curve. The result indicates that the notified chemical is volatile (Mensink *et al*., 1995). However, as the notified chemical is a crystalline salt which decomposes at melting point of 250°C and has a high molecular weight of 880, the vapour

pressure is expected to be low. Therefore, the test results should be treated with caution.

TEST FACILITY Notox (1996b).

Water Solubility > 560 g/L at 20°C

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

Remarks In the preliminary test, 29.78 g of the test substance was added in portions over a period of three days to 50 mL of water while stirring, which continued for another seven days. Duplicate samples were taken and centrifuged. Supernatants were taken and analysed by HPLC. The water solubility of the test substance was estimated at >560 g/L. No main study was performed as the viscosity of the solution has become too high, with more test substance added, to allow stirring to occur.

The result indicates that the notified chemical is readily soluble in water (Mensink *et al*., 1995).

TEST FACILITY Notox (1996c).

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*t½ hours*
4	50	2,790
7	25	117,000
9	25	10,000

Remarks Preliminary tests were performed by placing the test solution (buffers of pH 4, 7 and 9) in a waterbath at 50ºC in the dark. A sample was taken from each test solution at 0, 2.4 and 120 h. The concentration of the test solution was determined using HPLC. During the preliminary tests significant hydrolysis was observed at pH 9. Therefore, test 1 was performed at pH values of 4, 7 and 9 in duplicate. Test solutions for pH 4 and 7 were placed in a waterbath at 70ºC and for pH 9 at 60ºC in the dark. Test concentrations at pH 4, 7 and 9 were measured at certain time intervals. On the basis of the results from test 1, a further test was performed. The test solutions were kept in a waterbath at 80ºC for pH 4 and 7 and at 70ºC for pH 9. The concentrations of the test substance were determined at certain time intervals. The logarithms of all relative concentrations were plotted against time for these pH values, and the half-lives extrapolated to 25ºC.

The results indicate that the notified chemical is hydrolytically stable within the environmental pH range (Mensink *et al*., 1995).

TEST FACILITY Notox (1996d).

Partition Coefficient (n-octanol/water) log Pow at 20°C <-4.48

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient (Shake-flask method).

Remarks The solubility of the test substance in n-octanol was determined by adding 0.98 g of the test substance in 25 mL n-octanol and stirring overnight at room temperature. A sample of 15 mL was taken from the octanol phase and centrifuged at 20°C. The supernatant was taken and further centrifuged. The final supernatant was extracted with 0.05% tetrabutylammoniumbromide in water. The aqueous phase of the extractions was taken and analysed using HPLC. The result of the water solubility test for the test substance was used in the determination of the partition coefficient which estimated to be $\leq 3.29 \times 10^{-5}$.

The log Pow was determined to be <-4.48 indicating the test substance has a poor affinity for n-octanol.

TEST FACILITY Notox (1996e).

Adsorption/Desorption – screening test log K_{oc} = 4.98 at 21°C.

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)*
1	0.6	4.8	11.3 x 10^4
2	1.8	5.5	4.34 x 10^4
3	0.6	7.3	12.9 x 10^4

REMARKS Samples of three soil types characterised with respect to pH, organic carbon content, particle size distribution, cation exchange capacity and exchangeable cations, and moisture content were used in the tests. In the adsorption step, duplicate wet soil/test solution mixtures and a wet soil/0.01 M $CaCl_2$ solution as soil control were prepared for each soil type. A control consisting of test solution with no soil was also prepared. The samples were shaken continuously for a period of time and left to equilibrate for 16 h. After equilibration, the samples were centrifuged to separate the phases and an aliquot was taken for analysis by HPLC. The desorption step was performed on samples that adsorbed >25%. The supernatant removed during the adsorption step was replaced with fresh 0.01M $CaCl_2$ solution and the process was repeated as in the adsorption step. Between <1.04 and <1.19 % desorbed.

The result indicates that the average log Koc of 4.98 is considered to be immobile in soil (McCall *et al* 1980).

TEST FACILITY Safepharm (1997b).

Dissociation Constant Not determined.

Remarks The notified chemical contains aryl sulfonate, carboxylate, phenol, and hydrazinium groups which have pKa values in the range of –1.0 to 1.0, 1.0 to 4.0, 8.0 to 10.0, and 7.0 to 10.0, respectively.

Particle Size Not determined.

Remarks Notified chemical is normally part of an aqueous solution

Flash Point Not determined.

Remarks Not applicable to solids

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY Notox (1996f).

Autoignition Temperature 250°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Notox (1996g).

Explosive Properties Non-explosive

METHOD 92/69/EEC A.14
TEST FACILITY Safepharm (1999).

Reactivity The notified chemical has no oxidising properties. It does not contain any molecular group that might act as an oxidising agent.

TEST FACILITY Notox (1995b).

Surface Tension 71.6 mN/m at 20°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The determination of the surface tension was performed by means of a ring tensiometer. A test concentration of 1.007 g/L for the notified chemical was used in the test. The sample vessel was raised until the ring was completely immersed in the test solution. Then it was slowly lowered until the maximum force was achieved to detach the ring from the liquid surface. The time was recorded from the transfer of the solution to the measurement vessel until immediately after each measurement, which was repeated until a constant surface tension was obtained.

Based on the determined surface tension of 71.6 mN/m at 20°C, the test substance is not considered to be surface active substance.
TEST FACILITY Notox (1996h).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 > 2000 mg/kg bw, low toxicity
Rat, acute dermal	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Severely irritating
Guinea pig, skin sensitisation - adjuvant test.	No evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 200 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro chromosomal aberration test in human peripheral lymphocytes	Non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain Rat/Wistar
Vehicle Distilled water

RESULTS

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

LD50 > 2000 mg/kg bw
Signs of Toxicity 4/5 females showed black skin on back and tail on day 2 only.

Effects in Organs	None
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Notox (1996i).

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Wistar
Vehicle	Distilled water
Type of dressing	Occlusive.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Red staining on the snout on days 1-4 in 2 animals of each sex and 1 female showed red staining of the neck on day 12. Three animals of each sex showed black staining of the neck on the border of the application site and 1 female showed a black snout during exposure.
Signs of Toxicity - Systemic	None
Effects in Organs	None
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Notox (1996j).

7.3. Acute toxicity – inhalation

Test not performed

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Distilled water.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.

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	1	1	0
Oedema	0	0	0	0	0	0

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

REMARKS	A Draize score of 1 was recorded in 1/3 animals at one hour.
CONCLUSION	The notified chemical is very slightly irritating to skin.
TEST FACILITY	Notox (1996k).

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	1.3	1.3	2	72 hours	0
Conjunctiva: chemosis	1.3	1.3	1.3	3	72 hours	0
Conjunctiva: discharge	0.3	0.3	0.3	1	24 hours	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	1	24 hours	0

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

Remarks – Results	Redness of the conjunctivae could not be scored at the 1 hour time point. Colouration effects on the nictitating membrane and lower eyelid persisted for 21 days.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	Notox (1996l).

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 96/54/EC B.6 Skin Sensitisation – maximisation test.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 25% topical: 25%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
induction phase	Induction Concentration: intradermal injection: 25% topical application: 25%
Signs of Irritation	Not scored due to coloration of the treated skin.
CHALLENGE PHASE	
1st challenge	topical application: 5, 10, and 25%

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group	5%	0/10	0/10
	10%	0/10	0/10
	25%	0/10	0/10
Control Group	5%	0/5	0/3
	10%	0/5	0/3
	25%	0/5	0/3

Remarks – Results: One control animal was found dead on day 25 and one control animal was removed from the study on day 24 after showing signs of ill health.

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

TEST FACILITY: Notox (1996m).

7.7. Repeat dose oral toxicity

TEST SUBSTANCE: Notified chemical.

METHOD: EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
- Species/Strain: Rat/Wistar
- Route of Administration: Oral – gavage.
- Exposure Information: Total exposure days: 28 days; Dose regimen: 7 days per week;
- Vehicle: Distilled water

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	
II (low dose)	5/sex	50	1 female
III (mid dose)	5/sex	200	
IV (high dose)	5/sex	1000	1 female

Mortality and Time to Death

One female in the low and high dose groups died during blood sampling. The report did not state the time of death.

Clinical Observations

Excessive salivation and black staining of faeces were seen in the high dose group.

No effects on body weights or food consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry: No significant findings

Haematology: The high-dose females had lower mean corpuscular haemoglobin concentration and increased red blood cell distribution width. However, changes were within historical control range.

Pathology

Macroscopic examination: Staining of the gastro-intestinal tract, mesenteric lymph nodes and kidneys was noted in mid and high dose animals.

Organ weights: A statistically significant increase in kidney/body weight ratios was observed in high dose males.

Microscopic examination: Kidneys of high dose animals showed an increased incidence and severity of degenerative change characterised by cortical tubular hyalin resorption bodies and this was more pronounced in males.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 200 mg/kg bw/day in this study, based on kidney effects in high dose animals.

TEST FACILITY Notox (1996n).

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 – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain *S. typhimurium*:
TA1535, TA1537, TA98, TA100

Metabolic Activation System Aroclor-induced rat liver S9 fraction

Concentration Range in Main Test
a) With metabolic activation: 0 - 5000 µg/plate.
b) Without metabolic activation: 0 - 5000 µg/plate.

Vehicle Distilled water

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	> 5000	> 5000	Not observed	Negative
Test 2		> 5000	Not observed	Negative
Absent				
Test 1	> 5000	> 5000	Not observed	Negative
Test 2		> 5000	Not observed	Negative

Remarks – Results

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

TEST FACILITY Notox (1996o).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69EEC B.10 In vitro Mammalian Cytogenetic Test.

Cell Type/Cell Line Human peripheral lymphocytes

Metabolic Activation System Aroclor-induced rat liver S9 fraction

Vehicle Culture medium

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1			
(1)	100, 333, 562, 1000*, 1778*, 3330*	3 h	24 h
(2)	562, 1000, 1778*, 3330*	3 h	48 h
Test 2	100, 333*, 1000*, 3330*, 5000	3 h	24 h
Absent			
Test 1			
(1)	100*, 333, 1000*, 1334, 1778*, 3330	24 h	24 h
(2)	333, 1000, 1334, 1778*, 3330	48 h	48 h
Test 2	100*, 333, 1000*, 1334*, 1778, 3330	24 h	24 h

*Above 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*
Present				
Test 1	1000			
(1)		>3330	Not observed	Negative
(2)		>3330	Not observed	Negative
Test 2		5000	Not observed	Negative
Absent				
Test 1	1000			
(1)		3330	Not observed	Negative
(2)		3330	Not observed	Negative
Test 2		1778	Not observed	Negative

CONCLUSION — The notified chemical was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY — Notox (1996p).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
EEC Directive 92/69, C.4 Biodegradation: determination of the "ready" biodegradability.

Inoculum — Activated sludge from a municipal sewage treatment plant.
Exposure Period — 28 days.
Auxiliary Solvent — None.
Analytical Monitoring —
Remarks – Method — The test concentration of 88 mg/2 litres used in the test was performed in duplicate. The test system consists of test suspension containing the test substance and inoculum, a blank control containing the inoculum, a positive control containing the reference substance sodium acetate. A toxicity control containing the test substance, reference substance and inoculum was also used. The test was started by bubbling CO_2 free air through the solution in test bottles which are connected to CO_2 adsorbers

containing the barium hydroxide solution. The CO_2 produced in each test bottle was determined by titrating the remaining $Ba(OH)_2$ with HCl solution. Titrations were made every second or third day during the first ten days and thereafter at least every fifth day until the 28 day.

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
28	< 10%	28	100% (approx.)

Remarks – Results: The results indicate that the degradation values calculated from the measurements performed during the test period revealed no significant degradation (<10%) of the test substance. In the toxicity control 21% degradation occurred in 14 days. This was below the 25% required as inhibitory. However, this was considered to have no overall effect on the outcome of the study. The positive control was degraded 73% in 14 days. Complete degradation was achieved at the end of the 28 day test period thus validating the inhibitory requirements of the test system.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable and shows some effects on microbes at a concentration of 44 mg/L.

TEST FACILITY: Notox (1996q).

8.1.2. Bioaccumulation

No bioaccumulation study was conducted. In view of the negative logPow and high water solubility, the bioaccumulation potential is considered to be low (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.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish-static.

Species	*Cyprinus carpio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Based on the range finding tests, a final test was performed in duplicate with seven carp per concentration in a static system. The nominal concentrations tested were 112 and 62 mg/L The test solutions were aerated continuously and illuminated 16 h daily. There was no feeding from 24 h before the test and during the test period. Mortality and other effects were recorded at 3, 26, 50, 72 and 96 h following the start of exposure. Samples were taken from the vessels containing 62 and 112 mg/L at t= 0 and 96 h to determine the stability of the test substance under test conditions. All test conditions were within the acceptable limits. A reference test using pentachlorophenol was also performed to check the sensitivity of the test system.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
62	64	7	0	0	0	0	0
112	115	7	0	0	0	0	0

LC50	> 112 mg/L at 96 hours.
NOEC	112 mg/L at 96 hours.
Remarks – Results	The results of the tests were based on the measured concentrations of the test substance. Analysis of the samples taken at 10 mg/L did not reveal reliable results. The analysis was repeated at 100 mg/L The results indicate that the test concentration at 100 mg/L under test conditions was stable for at least 96 h. Based on the recovery of 80-90% in the range finding test at 100 mg/L, the highest nominal concentration was determined to be 112 mg/L and a second nominal concentration of 62 mg/L was included. The measured concentrations ranged from 101-105% of the nominal concentrations.
CONCLUSION	The notified chemical is very slightly toxic to carp (Mensink *et al*., 1995).
TEST FACILITY	Notox (1996r).

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. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None.
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Based on the range finding test, nominal concentrations of 10, 22, 46, 100 and 220 mg/L were used in the definitive test. Daphnia were exposed for a maximum of 48 h and the test was performed in duplicate with 10 daphnia per vessel. The study area was maintained on a 16 h daylight photoperiod. No aeration of the test solution and no food were supplied during the test. The number of immobile daphnia were recorded after 24 and 48 h. A reference test using potassium dichromate was also used to check the sensitivity of the test system. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	10, 10	0, 0	0, 0
10	ND	10, 10	0, 0	0, 0
22	19	10, 10	0, 0	0, 0
46	40	10, 10	0, 0	0, 2
100	90	10, 10	0, 0	6, 4
220	270	10, 10	0, 0	10, 10

ND = not determined; * Daphnids could not be observed due to the opaqueness of the solutions

EC50	85 mg/L at 48 hours (CI: 71-108 mg/L)
NOEC	19 mg/L at 48 hours
Remarks - Results	All results were based on the measured concentration of the notified chemical. Analysis of samples taken after 48 h from 22 and 220 mg/L showed that the measured concentrations remained >80% of the nominal concentrations. At test concentration of 220 mg/L, daphnia were not able to be observed due to the opaqueness of the solutions.
CONCLUSION	The notified chemical is considered to be harmful to *Daphnia magna* (Mensink *et al.*, 1995).
TEST FACILITY	Notox (1996s).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range Nominal	1.0, 2.2, 4.6, 10, 22 and 46 mg/L
Auxiliary Solvent	ISO-medium
Water Hardness	Not stated
Analytical Monitoring	Spectrophotometry
Remarks – Method	On the basis of the range finding tests, the definitive test was then conducted by exposing growing algal cultures to the test substance concentrations varying from 1.0-46 mg/L for a period of 72 h. An additional indirect test was performed to examine if the test substance could indirectly inhibit the growth of the green algae by light absorption as a result of the colour of the test solutions at concentrations of 1.0, 4.6 and 46 mg/L. At the beginning of the test, cells were counted by microscope using counting chamber. Thereafter cell densities were determined by using UV-visible spectrometry. The concentrations of the test solutions were measured by HPLC and validated. At the end of the 72 h exposure, the measured concentrations had not decreased by more than 20%. A reference test using potassium dichromate was also performed to check the sensitivity of the test system. All test conditions were within the range of acceptability. Based on the curves for growth inhibition and growth rate reduction versus the logarithm of the nominal concentrations, EC50 values were obtained.

RESULTS

Biomass		*Growth*	
E_bC_{50} *mg/L at 0-72 h*	*NOEC mg/L*	E_rC_{50} *mg/L at 24-72 h*	E_rC_{50} *mg/L at 0-72 h*
1.3		8.2 (CI: 3.2 to 25 mg/L)	13.5 (CI: 10 to 20.5 mg/L)

Remarks – Results	All results were based on the nominal concentrations. Although the colour of the test solutions inhibited algal growth owing to absorption of wavelengths necessary for normal cell growth, this was only significant at the higher concentration of 100 mg/L. Hence, the inhibition of algal growth observed at lower concentrations was considered to be a toxic effect.

CONCLUSION	The notified chemical is considered to be toxic to algae (Mensink *et al.*, 1995).
TEST FACILITY	Notox (1996t).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Most of the dye will eventually be landfilled, mainly in a bound to paper form. However, some paper will be recycled and due to the dye's high water solubility, a greater proportion will remain in the aqueous phase. Recycling may take place in a number of centres throughout Australia. Assuming a worst-case situation in which the entire import volume (1000 kg) is released to sewer during recycling and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 2.7 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 0.7 µg/L.

Amount entering sewer annually	1000 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	0.7 µg/L (0.7 ppb)

Based on the respective dilution factors of 0 and 10 for inland and ocean discharges of effluents, the PECs of the notified chemical in freshwater and marine water may approximate 0.7 or 0.07 µg/L, respectively.

Fate
The notified chemical is not expected to bioaccumulate due to its high water solubility. Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, sulphur and nitrogen. As a consequence of its anionic nature, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments as indicated by its log Koc of 4.98.

9.1.2. Environment – effects assessment

In summary the aquatic toxicity data indicate:

Rainbow trout (*Oncorhynchus mykiss)*: 96 h LC50	>112 mg/L
Daphnia magna: 48 h EC50	85 mg/L
Algae *(Selenastrum capricornutum)*: 72 h E_bC50	1.3 mg/L

Using the lowest EC50 of 1.3 mg/L for algae, a predicted no effect concentration (PNEC) of 0.013 mg/L has been derived by dividing the LC50 value by a safety factor of 100 since toxicity data are available for all three trophic levels.

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 and widespread. Waste from the recycling process includes sludge which is dried and disposed

of to landfill, and any of the notified chemical partitioned to the supernatant water will be released to sewer.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is $5.4x10^{-2}$ and $5.4x10^{-3}$, for freshwater and marine water, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The most likely exposure route for the notified chemical is dermal. Dermal contact may occur if residues of the ink are left in the printer or on the cartridge. Exposure would then take place when the cartridge is changed or the copier serviced.

Office workers and service technicians will have low levels of exposure to the notified chemical.

9.2.2. Public health – exposure assessment

When use the cartridges, consumers may make dermal contact with the ink preparation containing the notified chemical where an attempt is made to repair some mechanical mishap involving the cartridges in the printer. As spent cartridges can be easily replaced by new ones without any contact with the ink content, this possibility is remote. On printed paper, the notified chemical will be contained in a cured state and will be inaccessible to human contact. The public will have low levels of exposure to the notified chemical based on its described use pattern.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity in rats. It is not a skin sensitiser in guinea pigs, but is slightly irritating to skin and severely irritating to eye in rabbits. In an oral repeat dose study in rats, the no observed adverse effect level (NOAEL) for the notified chemical was established as 200 mg/kg bw/day based on kidney effects in high dose animals. The notified chemical is not mutagenic to bacteria or clastogenic to human peripheral lymphocytes in vitro.

The notified chemical is classified as a severe eye irritant because of persistent staining of the low eyelid and nictitating membrane in rabbits, with the risk phrase R41 (Serious damage to eyes) assigned (NOHSC, 1999).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is likely to be harmful if eye exposure occurs. Based on the facts that the concentration of the notified chemical in the ink is low, the ink remains in the inkjet cartridge with little likelihood of leakage or rupture, and the ink is bound to the paper on which it is deposited, ocular contamination of the notified chemical which could result in toxic effects in humans will unlikely occur. However, cautions should be taken by the office workers and service technicians to avoid any eye contact.

The amount of the notified chemical to which a worker may be exposed is low, both because of the low volume involved in a likely contact scenario, and because the concentration of the notified chemical in the ink is low. Following printing application, the notified chemical will become bound to paper and will not be bioavailable. Proper instructions in the handling of inks, particularly in clean-up procedures in the event of accident, are given to workers via MSDS, labels and instruction manuals. The health risk to workers is considered to be low.

9.2.5. Public health – risk characterisation

From the point of importation to the end use of the ink preparation containing the notified chemical, the ink preparation is either enclosed in a cartridge made for insertion in inkjet printers or is present on printed-paper in a cured state. The notified chemical is therefore inaccessible to contact by the public and will remain so unless a cartridge (new or spent) is damaged. Any public exposure to the ink preparation that does occur is most likely to be dermal and of a minimal and transient nature. The notified chemical is present in the ink preparation at a low concentration. The risk to public health is assessed as low, however, cautions should be taken by the public to avoid contact with eyes.

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:

R41: Risk of serious damage to eyes.

According to the OECD (2003) Globally Harmonised System for the Classification and Labelling of Chemicals, the notified chemical is categorised as:

	Hazard category	***Hazard statement***
Serious eye damage/ eye irritation	1	Causes serious eye damage.
Chronic hazards to the aquatic environment	2	Toxic to aquatic life with long lasting effects

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 under the conditions of the settings described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R41: Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥10%: R41 (Risk of serious damage to eyes).
  - 5%≤conc≤10%: R36 (Irritating to eyes).

- Products containing more than 5% notified chemical and available to the public must carry the following safety directions on the label:
  - S2 (Keep out of reach of children).
  - S25 (Avoid contact with eyes).

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - CAUTION – Avoid contact with eyes.

- 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.

Public Health

- The following measures should be taken to minimise public exposure to the notified chemical:
  - CAUTION – Avoid contact with eyes.

Environment

- Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of in landfill or be destroyed through incineration

Emergency procedures

- Spills/release of the notified chemical should be handled by collecting the cartridge intact and landfilled. Contain the spill and absorb with sawdust, sand or earth. Place used absorbent in suitable sealed containers and follow state or local regulation for the disposal of the waste.

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 Subection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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