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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Cyan Dye 1

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

Director
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, 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, dissociation constant and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
EU, US and Switzerland.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Cyan 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 inks for use in 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 maximum of 3% 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 to 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 at a maximum of 3% 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 Purple crystalline solid.

Melting Point > 300°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Decomposed at 300°C without melting.
TEST FACILITY Hazleton (1994a).

Density 1541 kg/m^3 at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks The relative density of the notified chemical was determined by a gas pyknometric method. The sample cup was partially filled with the notified chemical and pressurised. The pressure reading was recorded after settling. The tests were repeated five times to allow a mean value to be determined.
TEST FACILITY Hazleton (1994a).

Vapour Pressure < 1.2 x 10^{-7} kPa at 20°C.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour pressure measured using the static method by means of capacitance manometer. Absolute vapour pressure was determined at approximately 146°C as 0.013 Pa. Since it was impossible to construct a vapour pressure versus temperature curve, an extrapolation was made to 20°C using the assumption that the slope of the curve was –2000. The vapour pressure was calculated to be 1.2x10^{-4} Pa.

The result indicates that the notified chemical is considered to be very slightly

volatile (Mensink *et al*., 1995)

TEST FACILITY Hazleton (1994a).

Water Solubility > 557 g/L at 20ºC

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

Remarks The solubility of the test substance in water was determined by the shake-flask method. Equivalent pairs of flasks were incubated in a thermostatted water bath, initially at 30°C for one, two and three days before transfer to another bath at 20°C where they were equilibrated for at least one day. Samples were taken from the flask and analysed. A preliminary test gave a water solubility of >0.6 g/mL as the limiting value since the absolute solubility was not able to be determined from the shake flask method.

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

TEST FACILITY Hazleton (1994a).

Hydrolysis as a Function of pH Hydrolytically stable

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

pH	*T (°C)*	*t½ days*
4	50	100
7	50	318
9	50	2263

Remarks The test was performed by placing the test solution (buffers of pH 4, 7 and 9) in a water bath at 50ºC in the dark. A sample was taken from each test solution after specified intervals. Changes in concentration with respect to time were determined. The concentration of the test solution was determined using HPLC. No significant hydrolysis was observed at pH 4, 7 and 9 over 5 days period.

The result indicates that the test substance is hydrolytically stable within the environmental pH range (Mensink *et al*., 1995).

TEST FACILITY Hazleton (1994a)

Partition Coefficient (n-octanol/water) log Pow at 20ºC = -3.6

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

Remarks Based on the preliminary estimate of the partition, two samples were prepared at each of the following octanol:water ratios: 200:1, 100:1 and 50:1. The samples were mixed for three hours and equilibrated for one hour at a test temperature of 20°C. After centrifugation and separation of the phases, the water and octanol phases were analysed for the test substance. The pH of the aqueous phase was also measured.

The log Pow was determined to be ≤-3.57 indicating the test substance has a poor affinity for n-octanol.

TEST FACILITY Hazleton (1994a).

Adsorption/Desorption – screening test log K_{oc} = 4.76 at 21.5°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	11.8×10^4
2	1.8	5.5	1.70×10^4
3	0.6	7.3	3.56×10^4

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/0.01M $CaCl_2$ 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 16 h. After equilibration, the samples were centrifuged to separate the phases and an aliquot was taken for analysis by spectrophotometrically. In the desorption step, the supernatant removed during the adsorption step was replaced with fresh 0.01 M $CaCl_2$ solution and the process was repeated as in the adsorption step. Between 0.871 and 5.12 % desorbed after the second desorption process.

The result indicates that the average log Koc of 4.76 is considered to be immobile in soil (McCall *et al.,* 1980).

TEST FACILITY — Safepharm (1997a).

Dissociation Constant — Not determined.

Remarks — The notified chemical contains aryl sulfonate groups which typically have pKa value of –1.0 to 1.0. The notified chemical is in a salt form and will be fully dissociated in water.

Particle Size — 0.4% of particles had a size < 75µm

METHOD — Manual sieve.
TEST FACILITY — Hazleton (1994a).

Flash Point — Not determined.

Remarks — The test is not applicable to solids.

Flammability Limits — Not highly flammable

METHOD — EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY — SEPC (1994).

Autoignition Temperature — > 420°C (not autoflammable)

METHOD — 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY — SEPC (1994).

Explosive Properties — Does not present a danger of explosion when subjected to heat, shock or friction.

METHOD — EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks — Flame observed from heat test with 2 mm and 6 mm orifices.
TEST FACILITY — SEPC (1994).

Reactivity — Not oxidizing

METHOD — EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks — Maximum burning rate of test mixture: 1.2 mm/s compared to 1.5 mm/s for the reference mixture.
Test Facility — SEPC (1994).

Surface Tension 68.4 mN/m at 20°C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks The surface tension was measured by a White Instruments Tension balance using the ring method. Aqueous solutions of the test substance were prepared at concentrations of 224 and 161 mg/mL and the surface tension measured at 20°C. Based on the determined surface tensions of 68.4 and 69.4 mN/m at test concentrations of 224 and 161 mg/mL, respectively, the test substance is not considered to be surface active.

TEST FACILITY Hazleton (1994a).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 = 150-1000 mg/kg bw, harmful
Rat, acute dermal	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	limited evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 150 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in CHO cells	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Crl:CD(SD)BR
Vehicle Water.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5/sex	50	None
2	5/sex	150	None

LD50 150-1000 mg/kg bw
Signs of Toxicity Squinting eyes in one male at 150 mg/kg bw (consistent with observations made in the screening study) and blue faeces in all animals. Body weights and body weight gain were not affected by treatment.
Effects in Organs None.
Remarks – Results A screening study was performed which indicated the LD_{50} was between 50 and 1000 mg/kg bw.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Hazleton (1994b).

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Sprague-Dawley
Vehicle	Purified water.
Type of dressing	Semi-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	None.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.

REMARKS: The notified chemical was applied as a 74.25% aqueous paste.

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

TEST FACILITY Pharmakon (1993a).

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	Purified 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	0.33	0.33	0.67	1	48 hours	0
Oedema	0	0	0	0	0	0

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

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Pharmakon (1993b).

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

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Pharmakon (1994).

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler test.
Species/Strain Guinea pig/albino Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 54% (as aqueous paste)
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
induction phase Three induction Courses
topical application: 54%
Signs of Irritation Mild irritation was observed during induction
CHALLENGE PHASE
1st challenge topical application: 54%

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group	54%	1/20	1/20
Control Group	54%	0/10	0/10

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

TEST FACILITY Pharmakon (1993c).

7.7. 28-Day 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/Sprague-Dawley
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week
Vehicle Water

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	5	0
III (mid dose)	5/sex	50	0
IV (high dose)	5/sex	150	0

Mortality and Time to Death
None.

Clinical Observations
In the high dose group, salivation and abnormal movement of the forelimbs were observed after day 9 for less than 30 minutes post-dosing. During weeks 3 and 4, these effects occurred for up to 1 hour post-dosing. Blue faeces were noted in all treated animals. High dose males gained less weight than controls in week 1.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No dose-related effects in clinical chemistry or haematology parameters were of biological significance.

Effects in Organs
The administration of the notified chemical did not affect the organ weights in the treated animals.

Pathology-macroscopic findings
Blue colouration of intestines was observed in the mid- and high-dose animals. Blue discolouration also occurred in stomach, duodenum and kidneys in the high-dose animals.

Histopathological findings
No abnormal finding in the histopathological studies.

REMARKS:
Signs of toxicity at 150 mg/kg/day, but based on absence of histopathological findings, the no observed adverse effects level is selected to be 150 mg/kg/day.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study.

TEST FACILITY Hazleton (1994c).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation and pre-incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	a) Test 1: 8 - 5000 µg/plate. b) Test 2: 312.5 - 5000 µg/plate.
Vehicle	Sterile purified water.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				

Test 1	None	None	None	Negative
Test 2		None	None	Negative
Absent				
Test 1	None	None	None	Negative
Test 2		None	None	Negative

Remarks – Results: A 1 hour preincubation step was included in the presence of S9 in test 2.

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

TEST FACILITY: Hazleton (1994d).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical.

METHOD: EC Directive 92/69 EEC B.10

Cell Type/Cell Line: Chinese Hamster Ovary cells.

Metabolic Activation System: Aroclor 1254-induced rat liver S9 fraction.

Vehicle: Culture medium.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hour)*	*Harvest Time (hour)*
Present			
Test 1			
Trial 1	12.02, 18.49, 28.44, 67.31, 103.6, 159.3, 245.1, 377.1, 580.1, 892.5, 1373, 2112, 3250, 5000	2	20
Trial 2	11.42, 17.56, 27.02, 41.57, 63.95, 98.38, 151.4, 232.9, 358.2, 551.1, 847.9, 1304, 2007, 3088, 4750	2	20
Trial 3	1049, 1311, 1638, 2048, 2560, 3200*, 4000*, 5000*	2	20
Test 2			
(1)	1049, 1311, 1638, 2048, 2560, 3200*, 4000*, 5000*	2	20
(2)	1049, 1311, 1638, 2048, 2560, 3200, 4000, 5000*	2	44
Absent			
Test 1			
Trial 1	12.02, 18.49, 28.44, 67.31, 103.6, 159.3, 245.1, 377.1, 580.1, 892.5, 1373, 2112, 3250, 5000	20	20
Trial 2	11.42, 17.56, 27.02, 41.57, 63.95*, 98.38*, 151.4*, 232.9, 358.2, 551.1, 847.9, 1304, 2007, 3088, 4750	20	20
Test 2			
(1)	20.18, 28.82*, 41.18*, 58.82*, 84.03, 120, 171.5, 245, 350, 500	20	20
(2)	9.886*, 20.18, 28.82, 41.18, 58.82, 84.03, 120, 171.5, 245, 350, 500	44	44

*Above cultures were selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1		5000	See remarks-results	Negative
Test 2		5000	See remarks-results	Negative
Absent				
Test 1		151.4	See remarks-results	Negative
Test 2		58.82	See remarks-results	Negative

Remarks – Results

Precipitation occurred during the preparation, but no concentrations were indicated in the report.

In the cultures without S9, the signs of toxicity were not consistent with higher concentrations.

CONCLUSION

The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY

Hazleton (1994e).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE

Notified chemical

METHOD

EC Directive 92/69 Annex V Method C4F

Inoculum

Intermediate sewage effluent from an intermediate stage of a small scale, primarily domestic sewage treatment works, filtered and aerated.

Exposure Period

28 days.

Auxiliary Solvent

None.

Analytical Monitoring

HPLC

Remarks – Method

For determination of microbial toxicity, nominal concentrations of the test substance ranging from 1 µg-10 g/L were incubated at 20°C for five days in darkened closed bottles connected to mercury manometers. The microbial toxicity (IC50) is that concentration of the test substance which lowers by 50% the Biochemical Oxygen Demand (BOD) of a reference substance over a 5 day period. Readings of the oxygen uptake from the manometer were taken daily for five days. The results indicate that the % inhibition based on the microbial toxicity were scattered around a nominal of 27-47% range. No calculation of the I50 value can be made.

For ready biodegradability testing, quadruplicate aliquots of test solutions at concentrations of 1 g/L and 0.1 g/L were incubated at 20°C for 28 days in darkened closed bottles connected to mercury manometers. Readings of the oxygen uptake from the manometer were taken daily for 28 days. The results were expressed as a percentage of the calculated theoretical BOD value for the test substance. The theoretical BOD for the reference sodium acetate was 102.4 mg O_2/L.

For BOD testing, duplicate test solutions at concentrations of 1 g/L and 100 mg/L were incubated at 20°C for five days in darkened closed bottles connected to mercury manometers. The test readings were very low despite the relatively high concentrations of test substance used. The

reading at the higher concentrations (1 g/L) was used for the BOD data analysis. The five-day BOD for the test substance was determined to be 11 mg O_2/g, <1% of the theoretical BOD of 1876 mg O_2/g.

Chemical Oxygen Demand was also conducted using six flasks and 10 mL of the test substance solution was added to three of the flasks. Two blanks containing water and one control using potassium hydrogen phthalate as the reference were used in the test. Reagents such as acidified mercuric sulphate solution, potassium dichromate and silver sulphate were added to the flasks. The mixture was heated to reflux for two hours and cooled to room temperature. The residual dichromate was then determined by titrating with standardised ferrous ammonium sulphate. The chemical oxygen demand was determined to be 880 mg O_2/g.

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
28	Not detectable	28	89.1%

Remarks – Results

It was observed that >65% biodegradability is reached by the reference by day 4, validating the requirements for the ready biodegradability test system. There was no significant oxygen uptake in the test samples indicating that the test substance did not biodegrade under the conditions of the test.

CONCLUSION

The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY

Hazleton (1994f).

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

EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static.

Species	*Brachydanio rerio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	43.7 mg $CaCO_3$/L
Analytical Monitoring	HPLC

Remarks – Method

A 96 h semi-static toxicity test was conducted with the renewal of the test media at 24 h intervals. The test vessels were ten litre glass aquaria containing 10 L of test medium. A nominal concentration of 100 mg/L for the test substance was used in the test aquarium. The other aquarium without the test substance was used as a control. Ten *B. rerio* were placed in each aquarium. The contents of each test vessel were gently aerated. The fish were not fed during the test. The fish exhibiting toxic symptoms were recorded at 1, 24, 48, 72 and 96 h. The symptoms were classified as no effects, mild toxic effects (increased cough frequency, swimming position in test vessels different to controls), severe toxic effects

(swimming abnormally or lying at the bottom of tank), and dead. 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 Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
100	114	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	The results of the tests were based on the mean measured concentrations of the test substance. The maximum concentration of the test substance causing no mortality to *B. rerio* after 96 h was observed to be 100 mg/L. As no toxic symptoms were observed the NOEC = 100 mg/L.
CONCLUSION	The notified chemical is very slightly toxic to carp (Mensink *et al*., 1995).
TEST FACILITY	Hazleton (1994g).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	Visible spectrophotometry
Remarks – Method	Based on the range-finding study, nominal concentrations of 15, 30, 60, 125, 250, 500, and 1000 mg/L for the notified chemical were used in the definitive test. Tissue culture plates were used as the test containers. There are 4 daphnia in each well for each test concentration and for the control. The culture plates were stored at a temperature of 22°C for the duration of the test. After 24 and 48 h exposure, the number of mobile and immobile daphnia were recorded. 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*	*Percent Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	4		
15	14.9	4	0	5
30	30.6	4	15	15
60	60.7	4	35	55
125	125.1	4	70	70
250	257.2	4	65	95
500	510.4	4	76.2	95.2
1000	1075.5	4	60	100

LC50	115 mg/L at 24 hours 66 mg/L at 48 hours (CI: 50.6-89.5 mg/L)
NOEC	30 mg/L at 48 hours

Remarks – Results	All results were based on the nominal concentrations of the test substance as the measured concentrations were within 20% of the nominal values. The notified chemical was found to cause significant increase in immobilisation of daphnia at or above 60 mg/L. Therefore, the NOEC was determined to be 30 mg/L.
CONCLUSION	The notified chemical is considered to be harmful to *Daphnia magna* (Mensink *et al.*, 1995).
TEST FACILITY	Euro Laboratories (1994)

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	0 - 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	HPLC
Remarks – Method	The test was conducted by exposing growing algal cultures to the nominal concentrations of the test substance at 4, 9, 21, 45 and 100 mg/L for a period of 72 h. 100 mL of each solution were added to four flasks. Four further flasks were prepared containing culture medium only and served as controls. Three out of each set of four flasks were inoculated with the test organisms. The remaining flasks were not inoculated and were used to determine the concentration of the notified chemical in the test media. The algal cultures were incubated in a temperature controlled, illuminated incubator for a period of 72 h. At approximately 24 h intervals after the start of the inoculation, samples were taken for cell counting using haemocytometer. At the end of the exposure, test conditions such as pH, temperature and light intensity were found to be within the range of acceptability.

RESULTS

Biomass	*Growth*	
E_bC_{50} *mg/L at 0 - 72 h*	E_rC_{50} *mg/L at 0 – 72 h*	*NOEC mg/L*
9.7	64.6	9

Remarks – Results	All results were based on the nominal concentrations of the test substance. The mean measured concentrations of the test substance were 86-87% of the nominal concentrations. There was no test substance found in test media with nominal concentrations of 9 and 4 mg/L. Significant interference by the test media precluded reliable determination of concentrations below 20 mg/L. The highest NOEC based on biomass or growth rate was 9 mg/L
CONCLUSION	The notified chemical is considered to be toxic to algae (Mensink *et al.*, 1995).
TEST FACILITY	Hazleton (1994h).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Sewage sludge.
Exposure Period	0.5 and 3 hours
Concentration Range Nominal	0 - 1000 mg/L
Remarks – Method	The test material was aerated for a period of 3 h at 21ºC in the presence of activated sewage sludge with the addition of a synthetic sewage as a respiratory substrate. A test concentration of 1000 mg/L (three replicate vessels) was used based on the preliminary range finding study. The rate of respiration was determined after 30 min and 3 h contact time and compared to the data for the control and reference material 3,5-dichlorophenol.
RESULTS	
IC50	> 1000 mg/L (3 hour)
NOEC	100-1000 mg/L
Remarks – Results	The percentage inhibition for the test substance ranged from –1 to 12 % with a mean of 8 %. Based on the results from the definitive test the NOEC was considered to lie in the range of 100 to 1000 mg/L. The validation criteria for the control respiration rates and the reference material EC50 values were satisfied.
CONCLUSION	The notified chemical is considered to be non-toxic to sewage treatment bacteria.
TEST FACILITY	Safepharm (1997b)

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 substance 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 immobile in soil through adsorption onto soil particles and sediments as indicated by its log Koc = 4.76.

9.1.2. Environment – effects assessment

In summary the aquatic toxicity data indicate:

Zebra fish (*Brachydanio rerio)*: 96 h LC50	>100 mg/L
Daphnia magna: 48 h LC50	66 mg/L
Algae *(Selenastrum capricornutum)*: 72 h E_bC50	9.7 mg/L

Using the lowest LC50 of 9.7 mg/L for algae, a predicted no effect concentration (PNEC) of 0.097 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 $7.2x10^{-3}$ and $7.2x10^{-4}$, 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 was harmful by acute oral administration, and of low toxicity by acute dermal exposure in rats. It was slightly irritating to skin and eye in rabbits, and a weak skin

sensitiser in guinea pigs. The NOAEL for the notified chemical was established as 150 mg/kg/day from a repeat oral dose study in rats. The notified chemical was not mutagenic in bacteria or clastogenic in CHO cells in vitro.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is likely to be harmful if swallowed and to exhibit serious effects on repeated or prolonged exposure. 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, ingestion 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 ingestion occurring.

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 less than 3%. 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 concentration of less than 3%. The risk to public health is assessed as 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:

Xn: R22 (Harmful if swallowed)

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***
Acute toxicity	4(oral)	Harmful if swallowed.
	5 (dermal)	May be harmful in contact with skin.
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 as 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:
  - Harmful: R22 (Harmful if swallowed)

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Cut-off concentrations:
    ≥25%: R22 (Harmful if swallowed)

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 - Do not swallow.

- 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 - Do not swallow.

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:

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Subsection 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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