File No: STD/1122

February 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Black Dye 3

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 Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is 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:

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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Black Dye 3

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toxikos Pty Ltd (ABN 30 095 051 791)
293 Waverly Road
MALVERN EAST VIC 3145

Hewlett-Packard Australia Pty Ltd (ACN 004 394 763)
31-41 Joseph Street
BLACKBURN VIC 3130

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

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

- Chemical name(s)
- Other name(s)
- CAS Number
- Molecular formula
- Structural formula
- Molecular weight
- Spectral data
- Purity
- Identity of toxic or hazardous impurities
- Non-hazardous impurities
- Identity of Additives/Adjuvants
- % Weight of additives/adjuvants
- Manufacture and import volume
- Test facility where this may identify original manufacturer

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Adsorption/desorption
- Acute inhalation toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Black Dye 3

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD Infrared, ^{1}H Nuclear Magnetic Resonance, Mass and Ultraviolet/Visible spectroscopy.

Remarks Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
High.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name Water
CAS No. 7732-18-5 *Weight %* > 10%.

Chemical Name Notified chemical related manufacturing process byproducts
CAS No. *Weight %* < 5%

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported into Australia as part of sealed inkjet printing cartridges. The volume of the cartridges ranges up to 100 mL. Cartridges will be delivered to consumers by road transport.

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

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

USE
The notified chemical is a dye used in preparations in ink-jet reprographic processes. The notified chemical will be imported as part of the dye in sealed ink-jet cartridges at a typical concentration of < 6%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not known.

IDENTITY OF MANUFACTURER/RECIPIENTS
The inkjet printing systems will be potentially supplied to offices nationwide.

TRANSPORTATION AND PACKAGING
Cartridges are transported by road inside cardboard cartons.

5.2. Operation Description

No reformulation or repackaging of the product occurs in Australia. The product is delivered to the end-user as it is imported into Australia. The sealed inkjet printing system will be handled by service technicians or office workers replacing the spent cartridges in the printer.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*

Importation/Waterside workers	10	4 hours per day	70 days per year
Storage and transport	100	6 hours per day	240 days per year
Office worker/Service technician	10 000	< 0.1 hours per day	20 days per year

Exposure Details
The notified chemical is contained in sealed cartridges. The volume of the notified chemical in any single cartridge will be approximately 6 mL. Normal handling, involving replacement of the cartridge would not normally result in exposure. Exposure would only result if the cartridge were faulty or ruptured or if the printed substrate is handled before the ink has completely dried.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported in sealed cartridges containing up to 100 mL of formulated ink (with less than 6% of the chemical). There will be no release to the environment due to reformulation or repackaging.

RELEASE OF CHEMICAL FROM USE
The ink cartridges are designed to prevent leakage and will not be opened 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. These will be changed by office workers and the public. However, if leakage or spillage does occur, the ink will be contained with absorbent material and disposed of in landfill in the normal office garbage along with the empty cartridges and print heads.

The sealed cartridges are contained within the printer until they are removed for disposal. Residual ink (< 10%) containing up to 18 kg of the notified chemical left in empty cartridges (< 0.6%) will most likely be disposed of to landfill.

Most of the notified chemical (> 99%) will be bound to 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 fiber separation and ink detachment from the fibers. The wastes are expected to go to trade waste sewers. The notifier estimated that about 50% of the ink printed on paper will enter paper recycling and up to 60% of the ink is expected to be recovered during recycling. Due to the low percentage of notified chemical in the ink and the widespread use, release to the aquatic compartment will be highly diffused. The chemical adsorbed to sludge during the recycling process will be disposed of to landfill.

5.5. Disposal
No special precautions are required. The substance enclosed in cartridges can be disposed of through the usual channels for handling domestic waste.

5.6. Public exposure
The public will be exposed to the dye after use, when it is expected to be fixed to the paper. Limited exposure may occur while changing inkjet cartridges, however this will be relatively infrequent and should only result in exposure to small quantities of the notified chemical.

Consumer exposure to the notified chemical via the printed paper or non-absorbent substrate has been estimated by the manufacturer. One kilogram of pure dye would be expected to produce several million sheets of A4 coloured text or graphics. Under worst-case conditions, each piece of A4 paper can be assumed to incorporate 1 mg of notified chemical and there may be 50% transfer on contact when handling printed paper or non-absorbent substrate (assuming only partially dry ink), giving exposure of 0.5 mg notified chemical per event.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Black powder.

Melting Point Decomposes before melting at 276°C.

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Determined with differential scanning calorimeter.
TEST FACILITY Toxikos (2004a).

Density 1620 kg/m^3 at 20°C.

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Measured using a Pycnometer.
TEST FACILITY Toxikos (2004a).

Vapour Pressure < 0.01 kPa.

Remarks Based on the structure of the notified chemical its melting point was predicted to be 353°C using a group contribution method. It was not possible to predict the boiling point, therefore, two theoretical calculations were performed. First, the estimated melting point was used as a worst-case for the boiling point (as this would have to be higher than the melting point). Secondly, the minimum boiling point to achieve a pressure above 10^{-5} Pa was determined by iteration. Since no melting point was detected below the main decomposition exotherm (around 260°C) it was assumed that the predicted melting point was accurate to within at least 90°C, that the theoretical boiling point was much higher and thus the vapour pressure of the notified chemical was likely to be <<0.01 kPa.

The Henry's Law constant (H) calculated from the molecular weight, measured water solubility, and the estimated vapour pressure according to the following equation: H = MW (g/mol) X Vapour Pressure (Pa)/Water Solubility (mg/L) was <1.9 X 10^{-8} Pa m^3/mol, indicating that the substance is not likely to be volatile from water or moist soil (Mensink e*t al*. 1995).
TEST FACILITY Toxikos (2004b).

Water Solubility 450 - 500 g/L at ambient temperature

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Based on related substances, it was anticipated that the notified chemical would gel or form a thick paste at high concentrations after shaking at 30°C. A series of solutions were prepared at increasing concentrations (14.2 to 49.8% w/w). These were left in a shaking water bath at 30 ± 1°C for a day. The samples with higher concentrations were stirred and left for a further day. After allowing the samples to equilibrate at room temperature the samples were examined visually and with a spatula inserted for the presence of solid. Those below 40% were completely in solution, but at 40-50% these were pastes, with some insolubles close to 50%.

The notified chemical is readily soluble (Mensink *et al.* 1995).
TEST FACILITY Toxikos (2004a).

Surface Tension 72.4 mN/m at 25ºC

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: 0.1%. Two tests were run for 30 minutes using a Krüss K12 Tensiometer and the Wilhelmy plate method. The notified chemical is judged not to be surface active.
TEST FACILITY Toxikos (2004a).

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)*	*% hydrolysis after 5 days*
4	50	<10
7	50	<10
9	50	<10

Remarks Solutions were analysed by HPLC. The notified chemical can be considered to be hydrolytically stable at pH 4, 7 and 9 (Mensink *et al.*, 1995).

TEST FACILITY Toxikos (2004a).

Partition Coefficient (n-octanol/water) log P_{ow} at 25ºC = -3.3

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Concentrations of the notified chemical in water phases were determined spectrophotometrically by comparison to a calibrated curve prepared in distilled/deionised water containing 50% v/v n-octanol saturated water. The n-octanol phases were examined directly without dilution and as no appreciable absorbance due to the notified chemical was obtained, a detection limit was determined.

The low log P_{ow} is consistent with the high water solubility
TEST FACILITY Toxikos (2004a).

Adsorption/Desorption Not determined.

Remarks Not expected to adsorb to organic matter in soil, but will adhere to cellulose fibres on paper.

Dissociation Constant $pKa_1 = 11.0$
$pKa_2 = 2.0$

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks The pKa was investigated spectrophotometrically (UV/Vis) using dilute aqueous solutions of the notified chemical. The ionic strength of the solution was maintained at a constant level by the addition of potassium chloride (0.15M).
TEST FACILITY Toxikos (2004a).

Particle Size Not determined.
Remarks The notified chemical is introduced only in solution form.

Flash Point Not applicable to solids.

Flammability Limits Not flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Substance did not propagate combustion and did not spontaneously ignite.
TEST FACILITY Toxikos (2004b).

Autoignition Temperature 238°C.

METHOD EC Directive 92/69/EEC A.16 Self Ignition Temperature for Solids
TEST FACILITY Toxikos (2004b).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Mechanical Sensitivity
TEST FACILITY Toxikos (2004b).

Oxidising Properties Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Determination of Oxidising Properties

Remarks The notified chemical was assessed as non-oxidising by consideration of the results of a test on a close analogue and by consideration of the structure.
TEST FACILITY Toxikos (2004c).

Stability Testing Stable.

METHOD Heating at 54°C for 14 days with subsequent HPLC analysis.
Remarks No change in test substance.
TEST FACILITY Toxikos (2004a).

Reactivity

Remarks The notified chemical is expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD_{50} > 2500 mg/kg	low toxicity
Rat, acute dermal LD_{50} > 2000 mg/kg	low toxicity
Rat, acute inhalation toxicity	data not provided
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation - local lymph node assay	no conclusive evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOEL = 1000 mg/kg/day bw in males and 15 mg/kg/day bw in females
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – chromosome aberration	non clastogenic
Genotoxicity – in vivo	not conducted

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat /Sprague Dawley.
Vehicle Deionised water.
Remarks – Method None.

RESULTS

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

LD50 > 2500 mg/kg
Signs of Toxicity Hunched posture, ataxia and black staining of urine and faeces. All animals appeared normal 3 or 4 days after dosing.
Effects in Organs None.
Remarks – Results The acute oral median lethal dose of the test material was estimated using the flow chart system in the acute toxic class method.

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

TEST FACILITY Safepharm Laboratories (2004a).

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain Rat /Sprague Dawley.
Vehicle Arachis oil BP
Type of dressing Semi-occlusive.
Remarks – Method None.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

LD50 > 2000 mg/kg bw.
Signs of Toxicity - Local None.
Signs of Toxicity - Systemic None.
Effects in Organs None.
Remarks – Results Black stained urine was noted in all animals one to three days after treatment.

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

TEST FACILITY Safepharm Laboratories (2004b).

7.3. Acute toxicity – inhalation

Data not provided.

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
Vehicle Deionised water.
Observation Period 3 days.
Type of Dressing Semi-Occlusive.
Remarks – Method Residual test material was removed by gentle swabbing with cotton wool soaked in methylated spirits prior to assessment.

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	1	0	0	1	24hr	0
Oedema	0	0	0	0	-	0

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

Remarks – Results The presence of black coloured staining of skin at application sites was noted.

CONCLUSION The notified chemical is slightly irritating to skin.

TEST FACILITY Safepharm Laboratories (2004c).

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
Observation Period	7 days.
Remarks – Method	None.

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	0.3	0.3	0.3	2	24hr	0
Conjunctiva: chemosis	0.3	0.3	0.3	2	24hr	0
Conjunctiva: discharge	0.3	0.3	0.3	2	24hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks – Results Black coloured staining was noted around all treated eyes throughout the study. Staining of ocular tissues resolved by 48 hours.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Safepharm Laboratories (2004d).

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 429 Skin Sensitisation – Local Lymph Node Assay
Species/Strain Mouse/CBA/Ca (CBA/CaBkl).
Vehicle DMSO
MAIN STUDY
Number of Animals Test Group: 4 Control Group: 4
Induction phase Maximum Non-irritating Concentration: > 10% (w/w)
Topical: 25 µL or 2.5%, 5% or 10% (w/w) dilutions.
Signs of Irritation Not reported.
Remarks – Method None.

RESULTS The maximum stimulation index was 2.5 at the top dose with no clear indication of a dose-response relationship.

Remarks – Results A stimulation index greater than 3.0 was not observed. Black coloured staining of test sites was noted throughout the experiment.

CONCLUSION The notified chemical may have skin sensitising ability but the test conditions did not reach the maximum attainable concentration. On the basis of the present information, no conclusion can be made.

TEST FACILITY Safepharm Laboratories (2004e).

7.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
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 Distilled water.
Remarks – Method In a preliminary range finding study the notified chemical was

administered at 15, 150 and 1000 mg/kg/day bw for 14 days to Sprague Dawley rats (6/sex). Dark faeces were noted in the high dose animals from day 2 onwards and slight reduction in bodyweight gain in occurred in the high dose animals. Therefore these dose levels were chosen for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	15	0/10
III (mid dose)	5/sex	150	0/10
IV (high dose)	5/sex	1000	0/10

Mortality and Time to Death
There were no deaths during the study.

Clinical Observations
Treatment related findings were confined to the presence of dark faeces from the animals and blue/orange staining of cage tray liners from Day 2 in the mid and high dose groups. Associated findings involved staining of the external body surface in both sexes on Day 27 in the high dose group. All functional, sensory reactivity and behavioural assessments were within normal parameters.

Body weight, body weight gain, food and water consumption were unaffected by treatment except for an increase in body weight in high dose males.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment related effects were detected in clinical chemistry or blood parameters. Statistically significant increases in plasma bilirubin levels were detected in mid and high dose females, however individual plasma bilirubin values were all within the expected normal ranges.

Effects in Organs
Mid and high dose female rats had an increased incidence of tubular basophilia/degeneration in the kidneys.

Remarks – Results
The plasma bilirubin levels in female rats at the mid and high dose group were elevated when compared to controls, but against historical levels are within acceptable limits. The increased bodyweight gain in male rats during Week 4 in the highest dose group is considered to be without toxicological importance, since isolated increases in bodyweight gain in these types of chemicals are unlikely to be associated with test material toxicity.

Toxicologically significant findings were confined to histopathological changes, identified as tubular basophilia/degeneration of the kidneys observed in relation to treatment for mid and high dose female rats. Although there was no effect on kidney weight or renal dysfunction and male rats were unaffected, the effect may represent an early indication of target organ toxicity, especially since nephropathology is a common consequence of repeated administration of coloured materials. The effect may indicate a continuing cellular response to the persistent accumulation of test material and/or its metabolites.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day for males and 15 mg/kg bw/day for females in this study based on kidney effects.

TEST FACILITY Safepharm Laboratories (2004f).

7.7 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, TA102.
Metabolic Activation System	Phenobarbitone/β-naphthoflavone-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 50 – 5000 µg/plate. b) Without metabolic activation: 50 – 5000 µg/plate.
Vehicle	Sterilised deionised water.
Remarks – Method	None.

RESULTS

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

Remarks – Results	Positive control substances readily induced mutations in the tester strains and negative controls were within historical levels. No significant increases in the revertant numbers were observed at any dose level in any strain.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (2004g).

7.8 Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human peripheral lymphocytes
Metabolic Activation System	Phenobarbitone/β-naphthoflavone-induced rat liver S9 fraction.
Vehicle	Minimal Essential Media (MEM).
Remarks – Method	None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	0, 625, 1250*, 2500* and 5000*	4h	24h
Test 2	0, 625, 1250*, 2500* and 5000*	4h	24h
Absent			
Test 1	0, 625, 1250*, 2500* and 5000*	4h	24h
Test 2	0, 625, 1250*, 2500* and 5000*	24h	24h

*Dose levels selected for metaphase analysis.

Remarks – Results	The test material did not induce a statistically significant increase in the frequency of cells with chromosome aberrations in either the presence or absence of liver enzyme metabolising system in either of two separate experiments. No toxicity was observed as indicated by depression of mitotic index at any dose. Positive controls gave the expected increases

	in chromosomal aberrations and negative controls were within historical limits.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	Safepharm Laboratories (2004h).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.

Inoculum	Centrifuged, washed and resuspended activated sludge from a sewage treatment works that treats predominantly domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None.
Analytical Monitoring	Chemical Oxygen Demand (COD).
Remarks – Method	Measurements were performed on the notified chemical (100 mg/L), reference substance (sodium acetate at 200 mg/L), blank and toxicity controls (containing the notified chemical at 100 mg/L and sodium acetate at 200 mg/L). The pH in all of the test bottles was measured and adjusted to 7.4 ± 0.2 as necessary and the test bottle temperatures were maintained at 22 ± 2°C.

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
6	<10	6	68
10	<12	10	71
15	<7	15	67
21	<5	21	59
28	<5	28	52

Remarks – Results: At the end of test period, the temperatures in the bottles were 22 ± 2°C and the pH values were 7.4 in the control, 7.3 to 7.4 in reference substance and 7.4 to 7.5 in the test substance bottles.

The results indicated that < 5% of the notified chemical degraded in 28 days. Degradation of the reference substance (68% after 6 days) indicates that the test system was valid.

CONCLUSION: The test substance is not readily biodegradable according to the OECD criteria requiring > 60% degradation within 10 days of commencement of the test.

TEST FACILITY: Toxikos (2004d).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test - Static.

Species	Rainbow trout (*Oncorhynchus mykiss)*
Exposure Period	96 hours.
Auxiliary Solvent	None.
Water Hardness	49.3 mg $CaCO_3$/L.
Analytical Monitoring	The concentrations of the test substance in the test solutions were measured in samples taken from the centre of the solutions at 0 and 96

hours using the high performance liquid chromatography (HPLC) method.

Remarks – Method: The test solution was prepared by adding a known amount of the test substance to 20 L of dilution water resulting in a dark blue/black solution. A single nominal concentration of 120 mg/L was tested.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	<0.045	10	0	0	0	0	0
120	120	10	0	0	0	0	0

LC50: >120 mg/L at 96 hours.

NOEC: 120 mg/L at 96 hours (the highest concentration tested).

Remarks – Results: The dissolved oxygen concentration (9.0 to 9.9 mgO_2/L in control and 9.0 to 9.8 mgO_2/L in the test substance solutions), pH (7.3 to 7.7 in control and 7.3 to 7.6 in test solutions) and temperature (14.7 to 15.3°C in control and 14.6 to 15.4°C d test solutions) were all satisfactorily maintained.

The results of the study showed that no mortalities were observed at the test concentration. It was not possible to observe symptoms of toxicity in the fish in the test solution due to the intensity of colour.

CONCLUSION: The notified chemical is practically non-toxic to fish.

TEST FACILITY: Toxikos (2004e).

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: 226 mg $CaCO_3/L$.

Analytical Monitoring: The concentrations of the test substance in the test solutions were measured at 0 and 48 hours using the HPLC method. Samples were taken from the excess test solutions at the start and from one replicate of the control and test solution at the end of test.

Remarks – Method: The test solution was prepared by adding a known amount of the test substance to 11 L of dilution water. After stirring for 15 minutes, the test solution was deep blue opaque in colour. A single nominal concentration of 120 mg/L was tested.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	<0.047	20	0	0
120	120	20	-*	0

*It was not possible to make observations due to the intense colour of the test solution.

LC50: >120 mg/L at 48 hours.

NOEC: 120 mg/L at 48 hours (the highest concentration tested).

Remarks – Results: The dissolved oxygen concentration (9.4 to 9.8 mgO_2/L in control and

9.4 mgO_2/L in the test substance solutions) and pH (8.0 to 8.1 in control and 7.8 to 8.0 in test solutions) were satisfactorily maintained. The temperature was maintained at 20 ± 1°C (19.6, 19.9 and 19.8°C at 0, 24 and 48 hours).

No immobilised daphnids were observed after 48 hours in any test vessel. It was not possible to make observations at 24 hours due to the intensity of the colour of the test solution. The report states that no symptoms of toxicity were observed in the study, however, it should be noted that the intensity of colour would have made it difficult to detect these. The report does not indicate whether the test solution remained clear.

CONCLUSION The notified chemical is practically non-toxic to *Daphnia magna*.

TEST FACILITY Toxikos (2004f).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum*
Exposure Period	72 hours.
Concentration Range Nominal	0, 0.041, 0.091, 0.20, 0.45, 1.0, 2.3 and 5.0 mg/L
Concentration Range Actual	<0.0025, 0.042, 0.11, 0.27, 0.69, 1.4, 2.9 and 5.5 mg/L at 72 hours
Auxiliary Solvent	None.
Water Hardness	Standard culture medium was used.
Analytical Monitoring	The concentrations of the test substance in the test solutions were measured at 0 and 72 hours using the HPLC method. Samples were taken from the excess test solutions at the start and from the remaining blank solutions at the end of test.
Remarks – Method	The test solutions ranged from very pale blue to very dark blue (increasing intensity with concentration). Each replicate test vessel was inoculated to give a initial cell density of 1.00 x 10^4 cells/mL. The test vessels were incubated under shaded and illuminated conditions (two replicates each of the illuminated and shaded conditions).

RESULTS

	*Biomass**		*Growth**	
	EbC50 mg/L at 72 h	*NOEC Biomass mg/L at 72h*	*ErC50 mg/L at 72 h*	*NOEC Growth mg/L at 72h*
Exposed solution	1.09 (1.03-1.16)#	0.27	5.2 (4.8->5.5)#	0.27
Shaded solution	1.66 (1.43-1.90)#	0.27	4.9 (4.6-5.2)#	0.27

* All results are based on mean measured test concentrations.
# 95% confidence limit.

Remarks – Results The test temperature in the incubator ranged from 23.7 to 24.9°C and remained within 24 ± 2°C. At the start of the test, the pH values were 7.4 in the controls and 7.4 to 7.5 in the test substance solutions. The pH increased in all test vessels (7.7 to 7.9 in the controls and 7.6 to 8.1 in test substance solutions) at the end of the test.

The report does not indicate any abnormalities observed in algal cells or whether the test solution remained clear. Analysis of test concentrations showed that the mean measured concentrations ranged from 100 to 149% of the nominal values. The mean measured concentrations were used for

	calculating the EC50 values. Graphical comparisons of the percentages of inhibition in the exposure and shaded vessels showed that these curves were essentially the same. Inhibition of growth rate in exposure vessels plotted (%E) against that in shaded vessels (%S) showed that the curve follows the theoretical line plotted when %E = %S. This result indicated that the light absorbing properties of the test substance were a significant factor in the inhibition and therefore, it is not possible to distinguish reduced growth due to toxic effects from those due to differences in illumination.
CONCLUSION	The report indicates that the test substance satisfies the exemption clause in Annex VI (Dir.93/21/EEC) and the 72-hour EC50 for algae should not be used as a basis for classification of the test substance.
TEST FACILITY	Toxikos (2004g).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure of the notified chemical will result from the disposal of cartridges, printed paper and any leaked ink containing the chemical during the use of the cartridges. The total import volume of the notified chemical will ultimately be either disposed of to landfill, incinerated or recycled with paper.

The notified chemical is not volatile, therefore, will not dissipate into air. It is water soluble and is expected to remain within the aquatic environment but will not readily hydrolyse in natural waters at environmental pH values. The low log P_{ow} is consistent with the high water solubility indicating a low affinity for the organic phase and components of soils and sediments. It can be highly mobile in soil and, although not expected to adsorb to organic matter in soil, will adhere to cellulose fibres on paper.

Although not readily biodegradable, it is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified chemical due to abiotic or slow biotic processes. Incineration of waste paper and sludge will destroy the notified chemical with the generation of water vapour and oxides of carbon, nitrogen and sulphur plus metal salts.

Recycling may take place in a number of centres throughout Australia. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30 - 60% of the total amount of ink and therefore, at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. However, a greater proportion can be expected to remain in the aqueous phase due to the high water solubility of the notified chemical.

A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where the entire import volume (the maximum of 3000 kg) of the notified chemical will be used on paper and 50% of the printed paper will be recycled with 60% of the chemical remaining in the aqueous phase during the recycling process. Under this scenario 900 kg of the notified chemical per year will be discharged to sewer and if assume that none is attenuated within the sewage treatment plants (STP), the daily release on a nationwide basis to receiving waters is estimated to be 2.47 kg/day.

Assuming a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the worst-case predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 0.6164 µg/L. Based on the respective dilution factors of 1 and 10 for inland and ocean discharges of effluents, the PECs of the notified

chemical in freshwater and marine water may approximate 0.6164 and 0.0616 µg/L, respectively.

The notified chemical is not readily biodegradable. Its Henry's Law Constant of less than 1.9×10^{-8} Pa m^3/mol (log H < -6.72) and log P_{ow} of <-3.3, which are both limit values were applied in the SIMPLETREAT model (European Commission 2003) for modelling partitioning and losses in STPs. The results indicate that when 900 kg of the notified chemical is released into the aqueous phase of a STP, 0% released to air through volatilisation, 0% partitioned to biosolids and 100% (900 kg) partitioned to water. Therefore, the PECs of the notified chemical in effluent released, freshwater and marine water will be the same as the worst-case PECs estimated above (i.e. approximately 0.6164, 0.6164 and 0.0616 µg/L, respectively).

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 0.6164 µg /L may potentially result in a soil concentration of approximately 6.2×10^{-3} mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.1×10^{-2} mg/kg and 6.2×10^{-2} mg/kg, respectively.

Due to the low log P_{ow} and the high water solubility of the notified chemical, its potential for bioaccumulation is low in exposed aquatic organisms.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	*Duration*	*End Point*	*mg/L*
Fish	96-h	LC50	>120
Daphnia	48-h	EC50	>120

The results obtained for algal growth inhibition are concluded to be influenced by the light absorbing properties of the notified chemical. As it was not possible to distinguish toxic effects from reduced growth due to light attenuation, the results of the algae toxicity study could not be used as a basis for classification of the test substance.

A predicted no effect concentration (PNEC - aquatic ecosystems) of > 0.12 mg/L (>120 µg/L) has been derived by dividing the end point value of >120 mg/L by a worst-case scenario uncertainty (safety) factor of 1000 (as usable toxicity data are available only for two trophic levels).

9.1.3. Environment – risk characterisation

Location	PEC* µg/L	PNEC µg/L	Risk Quotient (RQ)*
Australia-wide STPs			
Ocean outfall	0.0616	> 120	$< 5.1 \times 10^{-4}$
Inland River	0.6164	> 120	$< 5.1 \times 10^{-3}$

* PEC and the RQ values calculated assuming 100% of the notified chemical partitioned into to water during the STP process (based on the SIMPLETREAT model).

The RQ values (PEC/PNEC) derived for the aquatic environment (assuming nationwide use, only 50% of the printed paper recycled and 60% of the notified chemical partitioned to water in STP) are considerably below 1 for both freshwater and marine water, indicating no immediate concern to the aquatic compartment. Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life. Bioaccumulation is not expected from the diffuse use pattern and low import volume. Based on low exposure potential from effluent for agricultural purposes, it is unlikely to result in unacceptable risk to soil

organisms.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

There is low potential for worker exposure to the notified chemical when replacing spent cartridges as it is at low concentration (< 6%) in the ink formulations which are sealed within the cartridge. Service technicians may occasionally experience skin contact with the notified chemical during maintenance; however, the notified chemical is at low concentrations in the ink formulations. Exposure to the notified chemical on printed paper is low as the dye is bound to the paper matrix. Some intermittent exposure may occur if printing onto a non-absorbent substrate occurs and the ink does not dry for a time.

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached.

9.2.2. Public health – exposure assessment

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 ink jet printers or is present on printed paper in a cured state. Public exposure through importation, transportation or storage is assessed as negligible. There is little potential for exposure during cartridge changes. Any exposure to the ink preparation that does occur is most likely to be dermal and of a minimal and transient nature. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available. Public exposure is assessed as low.

Assuming 1 mg of ink per A4 page, a worst case of 50% transfer of undried ink to fingers and the relative areas of finger ends and paper size, it is estimated that potential removal is < 1% of the applied ink in each event.

Area of contact with finger ends (four fingers on one hand) = 8 cm^2
A4 sized paper substrate = ca. 600 cm^2

% Removal = (8/600) × 0.5 × 100 = < 1%

Therefore total removal to finger ends at point of contact would be < 1% of 1 mg notified chemical per event = < 0.01 mg. Assuming 10 events per day, exposure may be up to 0.1 mg/day.

9.2.3. Human health - effects assessment

The notified chemical has a molecular weight only slightly less than 1000 and a low octanol/water partition coefficient, indicating a low degree of lipophilicity and low potential to cross biological membranes.

The notified chemical was reported to be of low acute oral and dermal toxicity with median lethal doses of > 2500 mg/kg and > 2000 mg/kg, respectively. Irritation studies in the rabbit indicated the notified chemical caused mild irritation to the skin and eyes. A local lymph node assay in the mouse revealed no evidence of reactions indicative of skin sensitisation at concentrations up to 10% (w/w) but a positive response at higher concentrations cannot be ruled out. No genotoxic effects were observed in a bacterial reverse mutation test or chromosome aberration test in human lymphocytes. A 28-day repeat dose study revealed the notified chemical was of low toxicity in male rats (NOEL = 1000 mg/kg/day bw) but kidney effects were observed in females at 150 mg/kg/day bw.

Black Dye 3 is not determined to be hazardous in accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2003) based on the data available at the time of the assessment.

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low given that the notified chemical is present in the ink at < 6%, is not determined to be hazardous, and the ink is contained in enclosed cartridges.

9.2.5. Public health – risk characterisation

Members of the public are not likely to make contact with the notified chemical during cartridge changes unless the cartridge is ruptured or otherwise tampered with. Additionally the notified chemical is present at low concentrations in a formulation that is not classified as hazardous. Ink containing the notified chemical on the printed pages is bound to the paper and is not readily bioavailable, with a worst-case estimate of body burden of 0.0014 mg/kg/day based on transfer of 0.1 mg/day, assuming no washing between events for a 70 kg person and 100% absorption, would be < 0.01 × 10/70 = ca. 0.0014 mg/kg/day. Using the NOEL of 15 mg/kg/day from oral repeat dose study and a safety factor of 100, the margin of exposure can be calculated to be:

15/(0.0014 x 100) = 15/0.14 = 107

It is noted that the estimate based on 100% absorption is conservative, given that the notified chemical has a molecular weight of approximately 1000.

Therefore, based on the low hazard and low potential for exposure the risk to public health from exposure to the notified chemical is considered low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2003).

As a comparison only, the notified chemical also is not classified using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

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 negligible concern to public health when used in the intended manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). They are 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 notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing Black Dye 3 are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2003), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The empty cartridges and ink containing the notified chemical should be disposed of in landfill in accordance with federal, state and local regulations.

Emergency procedures

- Spills/release of the ink containing the notified chemical should be handled by containing the spill by soaking up with absorbent material (sawdust, sand or earth). Slowly vacuum or sweep the material/used absorbent into a bag or other sealable container for disposal.
- Do not allow material or contaminated packaging to enter drains, sewers or water courses. Do not flush into surface water or sanitary sewer system.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

Annex IV (Dir. 93/21/EEC) Cited from test report on algal inhibition test. Recommendation of the ad-hoc working group of experts on algal growth inhibition for the interpretation of test results of coloured substances (Vienna, 30-31 January 1996) adopted by Competent Authorities for the implementation of directive 67/548/EEC at the 51st CA meeting (Rome 5-7 June 1996).

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No.1488/94. European chemicals bureau, European Communities.

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H. and Linders JBHJ (1995) Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. Report No. 679101022. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands.

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

NOHSC. (2003). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2003)]. Australian Government Publishing Service: Canberra.

NOHSC. (2003). National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(2003)]. Australian Government Publishing Service: Canberra.

OECD (2001). OECD Guideline for Testing of Chemicals 12: Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using HPLC.

Safepharm Laboratories Limited (2004a) [Notified Chemical] Acute Oral Toxicity in the Rat – Acute Toxic Class Method. SPL Project Number 780/364. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004b) [Notified Chemical] Acute Dermal Toxicity (Limit Test) in the Rat. SPL Project Number SPL 780/365. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004c) [Notified Chemical] Acute Dermal Irritation in the Rabbit. SPL Project Number 780/366. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004d) [Notified Chemical] Acute Eye Irritation in the Rabbit. SPL Project Number 780/367. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004e) [Notified Chemical] Skin Sensitisation – Local Lymph Node Assay in the Mouse. SPL Project Number 780/368. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004f) [Notified Chemical] Reverse Mutation Assay Ames Test using *Salmonella typhimurium*. SPL Project Number 780/371. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004g) [Notified Chemical] Chromosome Aberration Test in Human Lymphocytes. SPL Project Number 780/370. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Safepharm Laboratories Limited (2004h) [Notified Chemical] Twenty-Eight Day Repeated Dose Oral (Gavage) Toxicity Study in the Rat. SPL Project Number 780/369. Safepharm Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

Toxikos (2004a) Physical/Chemical Characterisation of [Notified Chemical] (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004b) Determination of Physical and Chemical Properties: [Notified Chemical] (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004c) Assessment of Oxidising Properties and the Potential to Evolve Flammable Gas on Contact with Water: [Notified Chemical] (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004d) Determination of 28-day Ready Biodegradability (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004e) Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004f) Acute Toxicity to *Daphnia magna* (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

Toxikos (2004g) Toxicity to the green alga *Selenastrum capricornutum* (unpublished report submitted by Toxikos Pty Ltd, Melbourne, Australia).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.