File No: LTD/1083

28 July 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MAGENTA DYE 2

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

MAGENTA DYE 2

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 names, CAS number, molecular and structural formula, molecular weight, spectral data, purity and impurities, concentration of the notified chemical in product, and import volumes.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
EU & USA.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Magenta Dye 2

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD: IR, UV/Vis, MS and NMR.

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
The notified chemical will be used as an ink dyestuff in colour inkjet cartridges.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Hewlett Packard Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component (<1%) in an aqueous formulation within a 24 mL sealed inkjet cartridges.

5.2. Operation Description

The notified chemical will not be manufactured, formulated or repackaged in Australia. The ready-to-use ink cartridge for inkjet printers containing the notified chemical will be used in offices and by the general public.

5.3. Occupational exposure

Exposure Details
The notifier did not provide any data of occupational exposure.

Office workers and printer service technicians may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, and during repair, maintenance and cleaning of the printing machine. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

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

5.4. Release

RELEASE OF CHEMICAL AT SITE
Not applicable

RELEASE OF CHEMICAL FROM USE
The notified chemical will be imported in the form of <1% w/w aqueous formulation in sealed tricolour inkjet cartridges. No release of the notified substance is expected during transportation, except in the event of an accidental spill. The MSDS contains suitable procedures for containing spills. The notified chemical is an ink dyestuff for use by the general public in colour inkjet electronic printers for producing quality prints. Very limited environmental release may occur indirectly from the disposal of printed paper (for recycling, to landfill or for incineration) and the disposal of spent ink cartridges at landfill sites. The notified chemical is very water-soluble and is expected to remain within the aquatic environment.

Following its use in Australia, the notifier indicated that virtually all of the notified chemical (1000 kg) will end up in paper and 92 % of the paper will be recycled (920 kg of the notified chemical). It was assumed that 60% de-inking occurred during the recycling process. Then the maximum volume of the notified chemical in sewerage system would be (0.6 x 920 kg) 552 kg, all of which will be disposed of to a liquid waste facility.

5.5. Disposal

The substance can be disposed of through the usual channels for handling domestic waste.

5.6. Public exposure

Public exposure to the notified chemical will occur through the use of inkjet printers. Although no exposure during normal use of the printers is expected, intermittent public exposure to the notified chemical is possible during changing cartridges or from clearing paper jams.

Public contact with the notified chemical will occur when handling printed paper but no exposure is expected as the ink is bound in the structure of the paper.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa A magenta powder.

Melting Point >400ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY Covance Laboratories Limited (2002a)

Density 1503.2 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY Covance Laboratories Limited (2002a)

Vapour Pressure 7.05 x 10^{-9} kPa at 20ºC
1.29 x 10^{-8} kPa at 25ºC.

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
REMARKS The vapour pressure of the notified chemical was measured by the Knudsen Effusion method which is based on an estimation of the mass of test substance flowing out of Knudsen cell per unit time, in the form of vapour, through a micro-orifice under high vacuum conditions. At varying time intervals, the oven pressure was brought to atmospheric, the crucibles reweighed and the loss in mass of test substance calculated using the Hertz-Knudsen relationship. Due to the hydroscopic nature of the test material, the result at 45ºC was discounted.

The result indicates that the notified chemical is very slightly volatile (Mensink *et al*., 1995).
TEST FACILITY Covance Laboratories Limited (2002a)

Water Solubility 235.8 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Six samples were prepared with an excess of test substance (ca 12.5 g) in 25 mL of distilled water. The closed flasks were stirred at 30°C for 1, 2 and 3 days and then transferred to another bath at 20°C for at lest 24 h. The solution were centrifuged to remove particulate matter. These extracts were analysed by HPLC and the pH of each test solution was measured at the time of sampling; the resultant pH was 7.7.

The result indicates that the notified chemical is readily soluble in water (Mensink *et al*., 1995).
TEST FACILITY Covance Laboratories Limited (2002a)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

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

pH	*T (°C)*	$t_{½}$
4	50	Stable
7	50	Stable
9	50	Stable

Remarks The test was performed over 5 days at 50°C at pH values of 4, 7 and 9. Samples were analysed by HPLC. At each pH value tested <10% of the test material was lost over the course of five days (maximum 8.3% at pH9). The test substance was hydrolytically stable within the environmental pH range.

TEST FACILITY Covance Laboratories Limited, (2002h)

Partition Coefficient (n-octanol/water) log Pow <1 at 30ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The octanol:water partition coefficient was determined by the HPLC simulation method using isocratic elution. The test substance eluted ahead of the most mobile reference substance acetanilide indicating the log Pow is <1 for the test substance.

TEST FACILITY Covance Laboratories Limited, (2002a)

Adsorption/Desorption – main test log K_{oc} <1.25 at 30°C

METHOD Proposed OECD Test Guideline 121 for the testing of chemicals

Remarks The distribution coefficient was estimated by the HPLC method using isocratic elution. The test substance was dissolved in methanol and the retention time recorded. The estimated distribution coefficient may be calculated from the calibration graph obtained using the reference compounds and the mean retention time of the test substance. The retention time for the test substance was found to be less than the reference compound acetanilide corresponding to a Koc less than the theoretical value of 1.25 for acetanilide.

TEST FACILITY Covance Laboratories Limited, (2002h)

Dissociation Constant

pK_{a1} 3.13
pK_{a2} 2.66
pK_{a3} 1.82
pK_{a4} 1.77

METHOD Proposed OECD Test Guideline 122 for the testing of chemicals

Remarks The dissociation constants of the test substance were determined using pH-metric titration. Four pK_a values were determined from the titration curves at 25°C.

TEST FACILITY Covance Laboratories Limited, (2002a)

Particle Size 18.7-33.1%(w/w) less than 38 µm

METHOD Airjet sieve screening technique.

Remarks The distribution of particle size was not provided. The test report indicates that static build-up may have caused the poor repeatability between the two sieve analyses.

TEST FACILITY Covance Laboratories Limited (2002a)

Flash Point Not determined.

Remarks The test was not conducted on a solid.

Flammability Limits Not flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical partially melted to a white residue over uncombusted powder that did not ignite. No flame/smoke were seen but very bright yellow/orange flashes/sparks were observed.
TEST FACILITY Covance Laboratories Limited (2001)

Autoignition Temperature 297.6°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The observed relative self-ignition temperature is 297.6°C. A second event occurred at 397.1°C, but the test ended at the temperature of 430°C.
TEST FACILITY Covance Laboratories Limited (2002a)

Explosive Properties Not an explosive hazard.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks The chemical structure indicates that the notified chemical does not posses explosive properties. This was supported by the calorimetry experiments which showed no explosive decompositions.
TEST FACILITY Covance Laboratories Limited (2002a)

Reactivity Not oxidising.

METHOD EC Directive 92/69/EEC A.17.
Remarks The notified chemical was not found to have a faster burning rate than the reference sample (barium nitrate).
TEST FACILITY Covance Laboratories Limited (2002a)

Surface Tension 71.3 mN/m at 20ºC for 1 g/L solution

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks A solution of test substance was prepared in distilled water at 1 g/L and its surface tension was measured using a Surface Tension (torsion) Balance following calibration by the ring method at 20°C.

The result indicates that the notified chemical is not surface active.
TEST FACILITY Covance Laboratories Limited (2002a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 >2 000 mg/kg bw, low toxicity
Rat, acute dermal	LD50 >2 000 mg/kg bw, low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	limited evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 150 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.

	EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague Dawley
Vehicle	Water
Remarks - Method	GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 male	2 000	0
2	3 female	2 000	0

LD50	>2 000 mg/kg bw
Signs of Toxicity	No clinical signs of toxicity were observed except pink/dark pink discolouration of the urine and outer visible skin surfaces.
Effects in Organs	None.
Remarks - Results	None.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Calvert Preclinical Services Inc (2001)

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/Cr1:WI
Vehicle	None.
Type of dressing	Semi-occlusive.
Remarks - Method	GLP & QA.
	A preliminary test on 2 males at 2 000 mg/kg was performed.
	The notified chemical was applied as a powder onto clipped and moistened dorsum.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2 000	0

LD50	> 2 000 mg/kg bw
Signs of Toxicity - Local	None.
Signs of Toxicity - Systemic	Pink discolouration of the fur, feet and tail and a pink tinge to voided faeces were observed.
Effects in Organs	None.
Remarks - Results	None.

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	Covance Laboratories Ltd (2002b).

7.3. Acute toxicity - inhalation

No inhalation study was 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	None.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS

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

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

Remarks - Results	Skin discolouration was observed.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	Covance Laboratories Ltd (2002c).

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	9 days
Remarks - Method	GLP & QA.

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	1	1	1	8 days	0
Conjunctiva: chemosis	0.7	0.7	0.3	2	48 hours	0
Conjunctiva: discharge	0.7	0	0	3	24 hours	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	Installation caused a slight initial sting response from all three treated rabbits. Installation into the conjunctival sac also caused transient staining

of the ocular structures which persisted for up to 5 days.

CONCLUSION — The notified chemical is slightly irritating to the eye.

TEST FACILITY — Covance Laboratories Ltd (2002d).

7.6. Skin sensitisation

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 406 Skin Sensitisation - maximisation.
EC Directive 96/54/EC B.6 Skin Sensitization – maximisation.

Species/Strain — Guinea pig/Dunkin-Hartley

PRELIMINARY STUDY — Maximum non-irritating concentration was difficult to determin in the preliminary study due to colouration of the applied sites.

MAIN STUDY

Number of Animals — Test Group: 10 Control Group: 5

INDUCTION PHASE — Induction Concentration:
intradermal injection 2.5% in water and/or adjuvant
topical application 40% in arachis oil

Signs of Irritation — Slight to well defined erythema was noted at the anterior injection sites after injections.

Assessment of erythema became impossible after induction injection and topical application due to the degree of pink staining.

CHALLENGE PHASE

1st challenge — topical application: 40% in arachis oil
topical application: 20% in arachis oil

Remarks - Method — GLP & QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after challenge*	
		24 h	*48 h*
Test Group	40%	1/7 (see remarks below)	0/9 (see remarks below)
	20%	0/10	0/10
Control Group	40%	0/5	0/5
	20%	0/5	0/5

Remarks - Results — At 24 hours, 3 sites challenged with 40% notified chemical were not scored because the pink stain prevents erythema reading. Similarly, at 48 hours, 1 site challenged with 40% notified chemical was not scored because the pink stain prevents erythema reading.

Slight oedema was observed in 4 sites at 24 hours.

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

TEST FACILITY — Covance Laboratories Ltd (2002e).

7.7. Repeat dose oral toxicity

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain — Cr1:WI

Route of Administration — Oral – gavage

Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 2 weeks.
Vehicle	Water.
Remarks - Method	GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	15	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	1 000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1 000	0

Mortality and Time to Death

None.

Clinical Observations

No treatment related effects were observed on bodyweight, food consumption and functional observation battery parameters including locomotor activity.

High-dose animals had salivation and paddling immediately post doses. High-dose animals and several mid-dose animals had pink colouration to the extremities and urine/faeces.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment related effects were observed on clinical chemistry, haematological tests and urinalysis except the high-dose animals had slightly lower mean alkaline phosphatase levels and slightly higher mean cholesterol levels.

Effects in Organs

Treatment related group mean adjusted thymus weight increase was observed in treated male animals, but became less significant in the females.

The change of group mean adjusted thymus weight was not seen in the recovery groups. However, group VI animals had a decrease in group mean adjusted spleen weight.

Pathology-macroscopic

Discolouration in the gastrointestinal tract and testis was observed in the treated animals.

Animals in the recovery group VI had a complete reversal of the discolouration in organs.

Pathology-microscopic

In the high-dose animals, there were minor tubular vacuolation in the kidney and foamy histiocyte accumulation in the lung. The effects in the lung were less severe in the mid- and low-dose animals.

Animals in the recovery group VI had a complete reversal of the renal tubular vacuolation and lung foamy histiocytes.

Remarks – Results

In the histopathological examinations, the changes in kidney and lung in high-dose group animals were considered to be treatment related. It is noted that these changes were partially reversed after a 14-day treatment free period.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on the histopathological changes at the high dose level.

TEST FACILITY	Covance Laboratories Ltd (2002f).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	Rat S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 0 – 5 000 µg/plate. b) Without metabolic activation: 0 – 5 000 µg/plate.
Vehicle	Water.
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	None.			
Test 1		None.	None.	None.
Present	None.			
Test 1		None.	None.	None.

Remarks - Results	The numbers of the revertant colonies of the negative control and the positive controls were within the range of the historical data in the testing laboratory.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Laboratory Inc (2001)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human peripheral blood lymphocytes
Metabolic Activation System	Rat S9 fraction
Vehicle	Water
Remarks - Method	GLP & QA.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	3200, 4000, 5000	3 h	20 h
Test 2	513.8, 1362, 2219	20 h	20 h
Present			
Test 1	3200, 4000, 5000	3 h	20 h
Test 2	2610, 4250, 5000	3 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		Not seen.	Not seen.	Not seen.
Test 2		2219	Not seen.	Not seen.
Present				
Test 1		Not seen.	Not seen.	Not seen.
Test 2		5000	Not seen.	Not seen.

Remarks - Results

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

TEST FACILITY Covance Laboratories Ltd (2002g).

7.10. Genotoxicity – in vivo

No study was provided for assessment.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1 Ready biodegradability

TEST SUBSTANCE Notified chemical

METHOD Commission Directive 92/69/EEC, C.4.B Biodegradability: Determination of ready biodegradability Carbon dioxide evolution test./OECD Guidelines for testing of chemicals Method No.301B

Inoculum Activated sludge
Exposure period 28 days
Auxiliary solvent None
Analytical monitoring None
Remarks - method The test substance was dissolved in buffered mineral salt medium which was inoculated with activated sludge. Test vessels were incubated in darkness at the temperature range of 20-22.6°C for 28 days. At intervals during the incubation, scrubbers were detached and their contents titrated with acid to determine the quantity of CO_2 purged from the test vessel. At the end of the incubation, the test vessel contents were acidified to release any residual CO_2 that had remained in solution. The experimental design consisted of both an inoculum blank control and a control which contained the activated sludge with the reference substance and the notified chemical. The controls were used to ensure that any lack of degradation of the test substance was not caused by self-inhibition. Degradation was calculated by expressing the blank-corrected cumulative recovered yield of CO_2 as a percentage of the theoretical yield calculated from the carbon content of the test substance.

RESULTS

Test substance		*Sodium Benzoate and test substance*		*Sodium Benzoate*	
Day	*%* degradation	*Day*	*%* degradation	*Day*	*%* degradation
2	2	2	38	2	39
4	4	4	54	4	54
6	8	6	67	6	64
8	11	8	75	8	70
10	14	10	80	10	73

14	15	14	85	14	79
16	16	16	90	16	84
21	16	21	96	21	89
23	17	23	100	23	94
28	19	28	104	28	99

Remarks- results The reference substance has attained >60% by day 6 confirming the validity of the study. Results from reference and test substance demonstrate no inhibition occurred. The notified chemical did not degrade beyond 20% over the course of the 28 day incubation and thus the notified chemical is not readily biodegradable.

TEST FACILITY Covance Laboratories Limited, (2002i)

8.1.2 Bioaccumulation

No test was conducted. However, given the high water solubility, predicted low fat solubility and minimal expected exposure of the chemical to the aquatic environment, bioaccumulation is unlikely to occur.

8.2 Ecotoxicological investigations

8.2.1 Acute toxicity to fish – Rainbow Trout

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test Semi-static.
Species *Oncorhynchus mykiss* (Rainbow Trout)
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness 96 mg $CaCO_3$/L
Analytical Monitoring HPLC analysis
Remarks – Method The study was conducted as a 96 h semi-static limit test (daily renewal) with a nominal exposure concentration of 100 mg/L. A control vessel was prepared using dilution water only. Ten O. *mykiss* were introduced into each test vessel which was aerated and the fish were not fed in the 24 h period preceding the test or during it. At approximately 1, 24, 48, 72 and 96 h during the test the fish were observed and the number exhibiting toxic symptoms such as swimming normally but exhibiting mild effects eg increased cough frequency, swimming position in test vessel different to controls, were recorded. A photoperiod of 16 h light : 8 h dark was established. Water parameters of temperature, dissolved oxygen and pH were measured throughout the tests 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*
0 (control)	<LOD	10	0	1*	0	0	0
100	77	10	0	0	0	0	0

* One fish found dead outside tank at 24 h for the control

LC50 >77 mg/L at 96 hours
NOEC >77 mg/L at 96 hours

Remarks- Results The initial measured concentrations of the notified chemical in 100 mg/L test treatment at 0 and 48 hours were 76.3 and 80.9 mg/L, respectively. At 24 and 72 hours, the measured concentrations of the notified chemical were 75.8 and 76.6 mg/L, respectively. The mean measured concentration of the notified chemical in the 100 mg/L test treatment was 77.4 mg/L. As the mean measured concentration of the notified chemical was not within 20% of the nominal exposure concentration,

the toxicity of the notified chemical to *O. mykiss* in the limit test was based on the mean measured exposure concentration.

There was no concentration related mortality during the test. After 96 h all fish exhibited mild toxic effects as described above. The mortality at 24 hours was not substance related. The LC50 values for O. mykiss exposed to the test substance were observed to be >77.4 mg/L.

CONCLUSION The notified chemical is considered at worst slightly toxic to Rainbow trout.

TEST FACILITY Covance Laboratories Limited, (2002j)

8.2.2 Acute/Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation - static.
Species Daphnia magna
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness 261 mg $CaCO_3$/L
Analytical Monitoring HPLC analysis
Remarks- Method A 48 h static toxicity test was carried out without renewal of the test media. The test medium was prepared by direct addition of the notified chemical to ASTM medium. A control treatment was prepared by the addition of the ASTM medium only to the test vessels. Five juvenile Daphnia were added to four replicate test vessels at each exposure concentration including the control group at the start of the exposure period. After 24 and 48 h the number of immobilised *D. magna* were recorded. Daphnia were considered to be immobilised if they were unable to swim for approximately 15 seconds after gentle agitation. A photoperiod of 16 h light : 8 h dark was established. Water parameters of temperature, dissolved oxygen and pH were measured throughout the tests and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<LOD	20	0	0
4.27	4.37	20	0	1*
9.39	9.72	20	0	0
20.7	21.3	20	0	0
45.5	46.6	20	0	0
100	104	20	0	0

* 1 daphnia was immobile but was not considered to be of biologically significant.

LC50 >100 mg/L at 48 hours
NOEC >100 mg/L at 48 hours

Remarks- Results No concentration related immobility was observed across all nominal exposure concentration. Mean measured concentration of the test substance ranged from 102-104% of the nominal exposure concentrations. The toxicity results are therefore based on the nominal exposure concentrations.

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

TEST FACILITY Covance Laboratories Limited, (2002k)

8.2.3 Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC, C.3 Algal Inhibition test/OECD Guideline for the Testing of Chemicals No 201 Alga, Growth Inhibition Test Species
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration range Nominal	0, 1.94, 4.27, 9.39, 20.7, 45.5, 100 mg/L
Concentration range Actual	0, 1.65, 3.75, 8.47, 18.7, 41.4, 91.8 mg/L
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	HPLC analysis
Results – remarks	A 100 mg/L test medium was prepared by the addition of the test substance to algal nutrient medium. Aliquots of the test medium were serially diluted to give the nominal concentrations listed above. The test medium was added to 8 flasks for the control and five flasks for each of the nominal concentrations. Three of the five flasks for each test concentration and six of the control flasks were inoculated with test organisms. Of the remaining two flasks per treatment, which were not inoculated, were used to determine the background count and for water quality monitoring. The flasks were then capped and incubated in a cool orbital incubator under constant illumination for an exposure period of 72 days. At approximately 24 h intervals aqueous samples were taken for cell counting from flasks inoculated with the algal cells and from the controls. The concentration of the notified chemical in aqueous test media was determined by HPLC analysis.

RESULTS

Biomass *Exposure solution mg/L at 72 h*	*Growth* *Exposure solutions mg/L at 72 h*
E_bC_{50} = 20.6 mg/L	E_rC_{50} >100 mg/L
NOEC ≤1.94 mg/L	NOEC 1.94 mg/L

E_bC50 = 20.6 mg/L
E_rC50 >100 mg/L

Remarks – Results	Mean measured concentration of the test substance ranged from 85-92% of the nominal exposure concentrations. The toxicity results were based on the nominal exposure concentrations. The notifier pointed out that effects on the growth rate (E_rC_{50}) are the preferred index of toxicity (European Commission (2002); Commission Directive (2001)). The effects on biomass may be due to the lower light intensity due to the colouration of the test substance and not a toxic effect of the notified substance.
CONCLUSION	The notified chemical is considered non-toxic to *Selenastrum capricormutum.*
TEST FACILITY	Covance Laboratories Limited, (2002l)

8.2.4 Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 87/302/EEC, C.11, Biodegradation: Activated Sludge Inhibition Test/OECD Guideline for the Testing of Chemicals No 209, Activated Sludge, Respiration Inhibition Test
Inoculum	Activated sludge

Exposure Period	3 hours
Concentration range Nominal	0, 1, 10, 100 1000 mg/L
Remarks - method	The experiment comprised a series of test mixtures containing a fixed quantity of synthetic sewage. Each aliquot of synthetic sewage was amended with appropriate volumes of water, test substance and reference substance. The test mixtures were completed sequentially at timed intervals by the adding of inoculum. The test preparations were incubated with aeration for 3 h. At the end of the incubation, electrochemical dissolved oxygen (DO) measurements were made on the test preparation using a DO meter and probe. The test substance was tested in duplicate at the nominal concentrations of 1, 10, 100 and 1000 mg/L. The reference inhibitor, 3,5-dichlorophenol was run at concentrations of 5, 15 and 45 mg/L.
RESULTS	
IC50	>1000 mg/L
Remarks - Results	No inhibition was observed at any test concentration. The concentration of the reference substance 3,5-dichlorophenol, causing a 50% reduction in respiration rate relative to untreated controls (EC_{50}), lay within the limits of 5 and 30 mg/L prescribed by the test Guideline. This response confirmed that the result was not a false negative caused by using an insufficiently sensitive activated sludge.
CONCLUSION	The notified chemical is considered non-toxic to micro-organisms.
TEST FACILITY	Covance Laboratories Limited, (2002m)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Using a worst case scenario based on release in Section 5.4, 552 kg of the notified chemical per year will be discharged to sewer and none is attenuated within these systems. Australia has a population of 19.5 million people and an average value for water consumption of 200 L/person/day has been adopted for this national-level assessment (3900 ML/day for total population). Therefore, the concentration for the notified chemical in the Australian sewerage network may approximate 3.6×10^{-4} mg/L (ie. 552×10^{6} mg $\div$ 365 days/year $\div$ 3900×10^{6} L = 3.6×10^{-4} mg/L). Based on dilution factors of 0 and 10 for inland and ocean discharges of STP-treated effluents, the predicted environmental concentrations (PECs) of the notified chemical in fresh water and marine surface waters may approximate 3.6×10^{-4} mg/L and 3.6×10^{-5} mg/L, respectively.

Using the SIMPLETREAT model for modelling partitioning and losses in sewage treatment plants (European Commission, 1996), the percentage removal from solution by STP may potentially approximate 0% through volatilisation and in sludge. Virtually all of the inflow concentration of the notified chemical may potentially remain in solution, passing through the STP. Thus the PEC concentrations in treated effluents and irrigation re-use waters may actually be 100% of that estimated with allowance for potential STP removal (ie estimated average effluent concentration of 3.6×10^{-4} and 3.6×10^{-5} mg/L for freshwater and marine waters, respectively).

The effluent re-use (eg. irrigation purposes) concentration of the notified chemical may potentially approximate 3.6×10^{-4} mg/L, assuming 100% remaining in solution during the STP process. STP effluent re-use for irrigation in Australia 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 3.6×10^{-4}

mg/L may potentially result in a soil concentration of approximately 3.6 x 10^{-2} mg/kg assuming accumulation of the notified chemical in soil for 10 years under repeated irrigation. Thus, 3.6 x 10^{-2} mg/kg is an estimated worst case PEC for the notified chemical in soils following effluent irrigation.

Fate

The notified chemical is very slightly volatile (1.29 x 10^{-5} Pa at 25°C) and loss to the atmosphere is unlikely to be significant from sewers and aquatic environment. It is not classified as ready biodegradable where it has attained 19% degradation after 28 day exposure with activated sewage sludge inoculum in the closed bottle test. It is highly soluble in water and is hydrolytically stable within the environmental pH range. It has a log Kow of <1 and a log Koc <1.25, indicating that it is unlikely to bioaccumulate and is highly mobile in soil.

9.1.2. Environment – effects assessment

In summary the toxicity data indicate:

Rainbow trout: 96 h LC50	>77 mg/L
Daphnia magna: 48 h LC50	>100 mg/L
Selenastrum capricornutum: 72 h ErC50	>100 mg/L
Micro-organisms: 3 h IC50	>1000 mg/L

Using the lowest LC50 of 77 mg/L for rainbow trout, a predicted no effect concentration (PNEC) of 7.7 x 10^{-1} mg/L has been derived by dividing the EC50 value by a safety factor of 100 since toxicity data are available for all three trophic levels.

Based on the available data the notified chemical should be classified and labelled as follows under the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals: *Chronic III*. The toxicity classification is based on toxicity to fish and possibly algae in the range of >10 mg/L to ≥100 mg/L and the lack of ready biodegradability

9.1.3. Environment – risk characterisation

Location	PEC (mg/L) or mg/kg	PNEC (mg/L)	Risk Quotient (RQ)[(a)]
Australia-wide STPs			
Ocean outfall	3.6 x 10^{-5} mg/L	7.7 x 10^{-1} mg/L	5 x 10^{-5}
Inland River	3.6 x 10^{-4} mg/L	7.7 x 10^{-1} mg/L	5 x 10^{-4}

a. RQ = PEC ÷ PNEC

On the basis of its low volumes used (ie. 1000 kg/year) and nationwide and diffuse use, the notified chemical is not considered to pose an unacceptable risk to the health of aquatic life based on its reported use and estimated disposal patterns. The low RQ value further indicates the unlikelihood of an environmental hazard to the aquatic life.

Based on low exposure potential and 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

The notified chemical will be imported in pre-packed inkjet cartridges. Dermal exposure of office workers to the notified chemical may occur when replacing spent cartridges and clearing paper jams from the printer. However, exposure will be low as there is a maximum of 60 mg notified chemical per cartridge.

During transport, storage and retail processes, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

9.2.2. Public health – exposure assessment

The public may be exposed to the notified chemical following transport accidents involving the breakage of cartridges. The total volume of spilled ink is likely to be small and readily contained for adsorption onto an inert material for mechanical collection, together with broken cartridges, for disposal as landfill. Any contact is likely to be dermal and of a minimal and transient nature.

In the course of the use of the cartridges, consumers may have 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. This possibility is remote and spent cartridges will be easily replaced by new ones without any contact with the ink content. On printed paper the notified chemical will be contained in a cured ink preparation and will be inaccessible to human contact. The potential for exposure of the public to the notified chemical is therefore low.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity in rats. It is non-irritating to skin but slightly irritating to eyes in rabbits. There was limited evidence of reactions indicative of skin sensitisation in guinea pigs. A NOAEL of 150 mg/kg/day is established from a 28-day repeat dose study in rats based on the histopathological changes in kidney and lung at the high dose level. The notified chemical is not mutagenic to bacteria in an Ames test, nor clastogenic in human lymphocytes in vitro.

Based on the available toxicity study reports provided by the notifier, the notified chemical is not classified as a hazardous substance.

9.2.4. Occupational health and safety – risk characterisation

The amount of the notified chemical to which a worker may be exposed is low, both because of the low volume involved in a likely contact scenario, and because the concentration of the notified chemical in the ink is low (<1%). Provided proper instruction in the handling of inks, particularly in clean-up procedures in the event of contact, are given to workers via MSDS, labels and instruction manuals, the 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 ink jet 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 by some mechanical means such an unlikely transport accident. The possibility of cartridge damage is slight. Any public exposure to the ink preparation that does occur is most likely to be dermal and of a minimal and transient nature. The notified chemical is present in the ink preparation at a low concentration. The risk to public health is therefore 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 not classified as a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999).

10.2. Environmental risk assessment

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 based on its reported use pattern.

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, 1994a). The MSDS of the notified chemical is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the products containing the 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

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practice to minimise occupational exposure to the notified chemical as introduced in the product:
  - Avoid dermal contact to the ink in the cartridges.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product:
  - Gloves.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

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

Public Health

- The following measures should be taken by consumers to minimise public exposure to the notified chemical:
  - Avoid dermal contact to the ink in the cartridges.

Disposal

- Dissolve or mix the material with a combustible solvent and burn in a chemical

incinerator equipped with an afterburner and scrubber. If large scale, contact a licensed contractor or an environmental professional for detailed recommendation. The notified chemical should be disposed of to sewer or landfill in accordance with local jurisdiction waste management guidance.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Stored in cool place and keep container closed.

Emergency procedures

- Spills/release of the notified chemical should be prevented from entering sewers or waterway.

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 Subsection 64(1) of the Act; if
  - concentration of the notified chemical in the product is greater than 1%.
  - introduction volume exceeds 1 tonne per year.

or

(2) 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.

13. BIBLIOGRAPHY

Calvert Preclinical Services Inc (2001) Acute oral toxicity study in the rat, Calvert Preclinical Services Inc, USA (unpublished report, provided by the notifier).

Commission Directive (2001) Official Journal of the European Communities No. L 225, 21.8.2001, p.1.

Covance Laboratories Ltd (2001) Evaluation of the spectroscopic properties and flammability, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002a) Determination of the physical-chemical properties, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002b) Acute dermal toxicity study in the rat, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002c) Skin irritation study in the rabbit, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002d) Eye irritation study in the rabbit, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002e) Skin sensitisation study in the guinea pig, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002f) 28 day oral (gavage) administration toxicity study in the rat with a 14 day treatment free period, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002g) Induction of chromosome aberrations in cultured human peripheral blood lymphocytes, Covance Laboratories Ltd, UK (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002h): Determination of the Hydrolysis (EC Test C7) and Soil Adsorption Coefficient [Screen] (Draft OECD 121) (Report No 1005/79). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002i) Ready Biodegradability by measurement of carbon dioxide evolution (Report No 1005/76). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002j) Acute toxicity to *Oncorhynchus mykiss* (Report No 1005/74). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002k) Acute toxicity to *Daphnia magna* (Report No 1005/88). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002l) 72h Inhibition of Growth to the Alga *Selenastrum capricornutum.* (Report No 1005/75). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

Covance Laboratories Ltd (2002m) Determination of inhibition of respiration of activated sludge. (Report No 1005/78). North Yorkshire, England, Covance Laboratories Limited (unpublished report, provided by the notifier).

European Commission (1996). Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for Existing Chemicals. Part II. Luxembourg.

European Commission (2002) Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC concerning the placing of biocidal products on the market. Part II, Chapter 3, Environmental Risk Assessment (Final Draft May 2002).

Laboratory Inc (2001) Reverse mutation test using micro-organisms, Laboratory Inc. (unpublished report, provided by the notifier).

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) 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 (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.