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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Yellow Dye 1

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd (ABN 74 004 394 763)
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:
Identity of chemical;
Composition;
Use; and
Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Flash point;
Particle size;
Dissociation constant; and
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU, US and Switzerland

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Yellow Dye 1

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of printing inks in pre-packed cartridges. The inks will contain a maximum of <5% notified chemical.

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

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

USE
As a dye in printing equipment.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne VIC

IDENTITY OF MANUFACTURER/RECIPIENTS
Hewlett Packard Australia Pty Ltd
31-41 Joseph Street
Blackburn VIC 3130

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by ship as pre-packaged cartridges. The cartridges will be packed in sturdy cardboard boxes and would normally be transported and distributed to customers by road.

5.2. Operation Description
No reformulation or repackaging of the product occurs in Australia. The sealed ink-jet cartridge is delivered to the end-user in its original packaging. The ink-jet cartridge will be handled by service technicians and office workers when replacing spent cartridges in the printer.

5.3. Occupational exposure
Number and Category of Workers

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

Exposure Details
Office workers and customer service engineers will replace spent ink cartridges. Replacement of printing cartridges involves removal of the old printing cartridge from the printing machine and directly loading the new cartridge. These workers may have dermal contact with very small quantities of the notified chemical if they touch the print heads while replacing cartridges, or on handling printed paper or film, particularly if the paper is handled before the ink is adequately dried or if printing to a non-absorbent substrate occurs by error. After the ink is dry the notified chemical is bound to the paper matrix and is not expected to be readily bioavailable.

Trained customer service engineers will maintain and clean printing machines.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release is expected as reformulation of the ink containing the notified chemical will not take place in Australia.

RELEASE OF CHEMICAL FROM USE
Release of the ink solution to the environment is not expected under normal use since the ink cartridges are designed to prevent leakage. If leakage or accidental spill occurs when changing spent cartridges, the ink will be contained with absorbent material, which will presumably be disposed of in landfill.

Ultimately, all of the notified chemical will be released to the environment. Printed paper to which the

notified chemical will be bound will eventually be buried in landfill or incinerated. The chemical may also be released in effluent from de-inking processes. Residues left in empty cartridges (estimated as <10% of ink) will most likely be disposed of to landfill.

Recycling of treated paper may result in the release of a small proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments which result in fibre separation and ink detachment from the fibres. The wastes are expected to go to trade waste sewers. It is estimated that about 20% of the ink printed on paper will enter paper recycling and up to 60% of the ink is recovered during recycling.

The low percentage of notified chemical in the ink and the paper recycling process contributes to low and highly diffuse release of the chemical to the aquatic compartment.

5.5. Disposal

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

5.6. Public exposure

The notified chemical will not be manufactured, reformulated or packaged in Australia. The imported inkjet cartridges may be transported by air, ship, rail, or truck to their distribution location. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. The design also prevents leakage of ink. Contact with very small quantities of ink during changing cartridges or on handling incompletely dried printed material may occur.

The public may be exposed to the notified chemical in the event of an accident during transport involving extensive breakage of cartridges.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Flaky solid.

Melting Point/Freezing Point > 250°C

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Melting point could not be determined due to decomposition, rearrangement or auto-oxidation.
TEST FACILITY	RCC Notox (1990a)

Density 1350 kg/m^3 at 20°C

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
REMARKS	The density of the test substance was determined using a gas comparison pycnometer, with helium as inert gas.
TEST FACILITY	RCC Notox (1990b)

Vapour Pressure < 0.037 kPa at 25°C.

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
REMARKS	Static vapour pressure measurements were made with a capacitance manometer. The sample cell was immersed in a thermostatically controlled container. The measurements were made at temperatures of 25, 33 and 39°C. In order to determine the vapour pressure at each temperature, the results in the vapour pressure readings were extrapolated to the first measurement at each series.
TEST FACILITY	RCC Notox (1990c)

Water Solubility Miscible in water at a 1:1 ratio.

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks A preliminary test was performed by adding 25.5 g of the test substance to 25 mL of distilled water. The mixture was stirred for 20 h at room temperature. Duplicate samples were taken and centrifuged. Both supernatants were analysed using HPLC. The mean value of the concentrations analysed was 1 x 10^3 g/L based on 1:1 (w/v) ratio.

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

TEST FACILITY RCC Notox (1990d)

Fat Solubility 0.0031 mg/100 g HB 307 at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.

Remarks In the preliminary test, approximately 1 g of the test substance was added to 25 mL liquefied standard fat (HB 307) and shaken for approximately 16.5 h at 37ºC. The concentration of the test substance was determined using HPLC. In the main study the concentration of the test substance in the fat phases was determined directly using HPLC after the shaking periods of 3, 24, 49 and 71 h. The results in the main study differed significantly from the preliminary test. This difference could be accounted for by the presence of the fine solid particles in the supernatant of the preliminary test. Solubility in fat is low.

TEST FACILITY RCC Notox (1990j)

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	>5 days
7	50	>5 days
9	50	>5 days

Remarks The test was performed by placing the test solution (buffers of pH 4, 7 and 9) in a waterbath at 50ºC in the dark. A sample was taken from each test solution at 0, 2.4 and 5 days. The concentration of the test solution was determined using HPLC. No significant hydrolysis was observed in the preliminary test over 5 days. The test substance was hydrolytically stable within the environmental pH range.

TEST FACILITY RCC Notox (1990e)

Partition Coefficient (n-octanol/water) log Pow at 20ºC estimated as ≤ -4.3

METHOD OECD TG 107 Partition Coefficient (n-octanol/water), Shake-flask Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The solubility of the test substance in n-octanol was determined by adding 0.19 g of the test substance to 50 mL n-octanol. After a stirring period of approximately 1.5 days, duplicate samples were taken and centrifuged at 20ºC. The supernatants were taken and centrifuged a second and third time. The final supernatant was taken and analysed using HPLC. The n-octanol solubility was found to be ≤ 5 x 10^{-2}g/L. Using the result of the water solubility test, the partition coefficient was determined to be ≤ 5 x 10^{-5}g/L.

TEST FACILITY RCC Notox (1990f)

Adsorption/Desorption log K_{oc} = 2.12.

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

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)*
1	0.6	4.8	246
2	1.8	5.5	60.2
3	0.6	7.3	88.1

Remarks Samples of three soil types characterised with respect to pH, organic carbon content, particle size distribution, cation exchange capacity and exchangeable cations and moisture content were used in the tests. In the adsorption step, duplicate wet soil/test solution mixtures and a wet soil/0.01 M $CaCl_2$ solution as soil control were prepared for each soil type. A control consisting of test solution with no soil was also prepared. The samples were shaken continuously for 16 h. After equilibration, the samples were centrifuged to separate the phases and an aliquot was taken for analysis by HPLC. In the desorption step, the supernatant removed during the adsorption step was replaced with fresh 0.01 M $CaCl_2$ solution and the process was repeated as in the adsorption step. Between 36 and 50% desorbed.

The average log Koc of 2.12 is considered to indicate high mobility in soil (McCall, 1980).

TEST FACILITY Safepharm Laboratories Limited (1997a)

Dissociation Constant Not determined

Remarks The notified chemical contains aryl sulfonate groups which typically have pKa value of –1.0 to 1.0 and carboxylate groups which have pKa values of 1.0 to 4.0. The notified chemical is in a salt form and will be fully dissociated in water.

Particle Size <1% of <100µm

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Remarks Mass median aerodynamic diameter was not determined since negligible particles of the notified chemical were found to be in the inhalable range (100µm).

TEST FACILITY Safepharm Laboratories Limited (1997a)

Surface Tension 71.3 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.

Remarks The determination of the surface tension was performed by means of a tensiometer based on the ring method of Lecomte de Noüy. The force which was required to withdraw a horizontally suspended ring from the surface of the solution is measured. After completing the measurement, the ring was immersed below the surface again and the measurements were repeated until a constant surface tension was reached. The time passed since the solution was transferred to the measurement was recorded for each measurement. Based on the determined surface tension of 71.3 mN/m, the test substance is not considered to be surface active substance.

TEST FACILITY RCC Notox (1990k)

Flash Point Not determined

Remarks The notified chemical is solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Test substance could not be ignited with a flame.
TEST FACILITY RCC Notox (1990g)

Autoignition Temperature Not autoflammable up to 400 °C.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY RCC Notox (1990h)

Explosive Properties Not thermally or mechanically explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY RCC Notox (1990i)

Oxidizing Properties No oxidising properties.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY RCC Notox (1990l)

Reactivity

Remarks The notified chemical is stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 95 mg/kg bw	toxic
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 1 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human peripheral lymphocytes	non genotoxic
Genotoxicity – in vivo mouse bone marrow micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Wistar
Vehicle Water prepared by reverse osmosis.
Remarks – Method A limit study of 5000 mg/kg bw was conducted. Since all animals died within 10 min of dosing, a Pilot Study was performed with 2 groups (1/sex), and treated at 500 or 50 mg/kg bw. All animals dosed at 500 mg/kg died within 1 hour following dosing and no mortality occurred among animals dosed at 50 mg/kg bw. Based on the result, dose levels of 320, 180 and 100 mg/kg bw were selected for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	100	40% males, 80% females (60% sexes combined)
2	5/sex	180	100%
3	5/sex	320	100%
4	5/sex	5000	100%

LD50	95 mg/kg bw (estimated); 104 mg/kg in males, 81 mg/kg females.
Signs of Toxicity	Convulsions, lethargy, ataxia, piloerection.
Effects in Organs	In the 5000 mg/kg group: red areas in the glandular stomach, dark red liver, dilated pelvis of the right kidney.
Remarks – Results	All deaths occurred within 24 hours of dosing except for 1 female at 100mg/kg, which was found dead on day 4. All surviving animals had recovered from systemic toxicity by day 6 and showed body weight gain over the period of the study.

CONCLUSION The notified chemical is toxic via the oral route.

TEST FACILITY RCC Notox (1991a)

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/Wistar
Vehicle	Water prepared by reverse osmosis.
Type of dressing	Occlusive
Remarks – Method	No significant protocol deviations..

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Yellow discouloration by the test substance in all animals. Small red wounds in 1 male.
Signs of Toxicity - Systemic	Lethargy on day 1 in 4/5 males and on day 2 in 4/4 males and females. One male showed piloerection on day 2.
Effects in Organs	Yellowish slimy content of the intestine in dead animals.
Remarks – Results	All animals showed bodyweight gain over the study period.

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

TEST FACILITY RCC Notox (1990m)

7.3. 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 females

Vehicle	Water prepared by reverse osmosis.
Observation Period	72 hours.
Type of Dressing	Occlusive.
Remarks – Method	No significant protocol deviations.

RESULTS

Remarks – Results	Yellow discolouration of treated area. Draize scores for erythema and oedema were zero in all animals during the 72-hour observation period.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY RCC Notox (1990n)

7.4. 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 females
Observation Period	7 days
Remarks – Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	1.7	0.7	2	72 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge						
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	Yellow discolouration by the test material of the head and eyelids was observed in all animals.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY RCC Notox (1990o)

7.5. Skin sensitisation

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 406 Skin Sensitisation – Buehler test.
EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler test.

Species/Strain	Guinea pig/Himalayan albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 25% w/w
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
induction phase	Induction Concentration: topical application: 10% w/w
Signs of Irritation	None.
CHALLENGE PHASE	

1st challenge	topical application: 10% w/w
Remarks – Method	Induction was conducted for 6 hours, 9 times over three weeks.

RESULTS

Remarks – Results	During the irritation pre-test, the animal treated with 50% w/w test material died the day after application. Symptoms preceding death included pale skin, tremors, lacrimation and hypothermia. During the main study, no signs of skin sensitisation and systemic toxicity were observed, and no mortality occurred.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	RCC Notox (1990p)

7.6. 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/Wistar
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: none
Vehicle	Water prepared by reverse osmosis; dose volume 5 mL/kg bw.
Remarks – Method	The maximum dose of 50 mg/kg/day bw was selected on the basis of effects at this dose in a 5-day range-finding study. On day 1, initial food weights were inadvertently not recorded; therefore food consumption during week 1 was determined as of day 4.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None
II (low dose)	5/sex	1	None
III (mid dose)	5/sex	10	None
IV (high dose)	5/sex	50	None

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

All high dose animals showed excessive salivation from day 16. On two occasions during week 2, regurgitation of the test substance occurred in 2 high dose females. Alopecia was observed in one high dose male between day 27 and day 29. Body weight, body weight gain and food consumption were not affected by treatment.

No abnormalities were found upon opthalmoscopical examination of animals except for a pallor of retina in one low dose male on week 4.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry:

Urea levels in high dose males were slightly decreased. Slightly higher calcium levels in high dose males were within historical limits. Alanine aminotransferase levels were elevated in high dose animals.

Haematology:
No significant differences were observed.

Effects in Organs

No macroscopic effects or changes in organ weights were observed. Microscopic examination of the kidneys revealed slight necrosis of the proximal tubules in high dose animals. Very slight tubular necrosis or tubular basophilia was noted in mid dose animals.

Remarks – Results
The alopecia observed in one high dose male is common in rats at this age and therefore not considered to be treatment related.

Slightly decreased urea in the blood serum of high dose animals may be the result of fluctuations due to the microscopic renal lesion. The cation of the notified chemical is known to exhibit a short half life due to active secretion into the tubules, probably by cells of the proximal tubule, which may provide an indication of the mechanism of toxicity observed in this study.

Salivation and regurgitation of test substance could be due to a bad taste of the test substance. However, the pharmacological effect of the notified chemical as a ganglion stimulating drug affecting the autonomic nerve system could activate the smooth muscle control and glandular secretion at low concentration of the notified chemical.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1 mg/kg bw/day in this study, based on microscopic kidney effects.

TEST FACILITY RCC Notox (1991b)

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. Preincubation procedure (Prival and Mitchell)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100
Metabolic Activation System	S9 fraction from livers of uninduced Syrian Golden Hamsters.
Concentration Range in Main Test	a) With metabolic activation: 100 - 5000 µg/plate. b) Without metabolic activation: 100 - 5000 µg/plate.
Vehicle	Water (test substance); Saline (-S9); Dimethylsulfoxide (+S9).
Remarks – Method	No significant protocol deviations.

RESULTS

Remarks – Results	Experiment 1 showed a nearly 2-fold increase in the number of revertants for TA1535 and TA100 tester strains in the absence of metabolic activation. This occurred at low dose, and no dose-response was seen. In Experiment 2, no substantial increase in the number of revertant colonies was seen in any strain either in the presence or absence of metabolic activation. Appropriate positive and negative control values were within background historical ranges, indicating that the test conditions were optimal and that the test system responded appropriately.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY	RCC Notox (1990p)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Human lymphocytes.
Metabolic Activation System	Aroclor 1254 induced rat liver S9.
Vehicle	Water.
Remarks – Method	No significant protocol deviation.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	0*, 39.06, 78.13, 156.25, 312.5, 625, 1250*, 2500*, 5000*	4 h	16 h
Test 2	0*, 312.5, 625, 1250*, 2500*, 5000*	4 h	16 h
	0*, 1250, 2500, 5000*	4 h	40 h
Absent			
Test 1	0*, 39.06, 78.13, 156.25, 312.5, 625, 1250*, 2500*, 5000*	20 h	20 h
Test 2	0*, 312.5, 625, 1250*, 2500*, 5000*	20 h	20 h
	0*, 1250, 2500, 5000*	44 h	44 h

*Cultures selected for metaphase analysis.

RESULTS

Remarks – Results	Neither cytotoxicity nor precipitation was observed in both experiments. In Experiment1, a single statistically significant increase in aberrant cells (without gaps) was recorded for 5000 μg/mL test concentration without metabolic activation. However, the frequency of cells with aberrations was low (2.5%) and when compared with a zero value for the control group, the number of aberrant cells became statistically significant. In Experiment 2, no statistically significant increase in the frequency of cells with chromosomal aberrations or polyploid cells either in the absence or presence of metabolic activation.
CONCLUSION	The notified chemical was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Safepharm Laboratories Limited (1998)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/Swiss
Route of Administration	Oral – intubation.
Vehicle	Water.
Remarks – Method	In a pilot study, 3 animals/sex/group were treated orally with 500, 300, 200 and 100 mg/kg bw test substance. Three animals dosed at 400 mg/kg, and one animal of 300 and 200 mg/kg bw each died within a few hours. Surviving animals at 400 mg/kg bw showed lethargy and ataxia, and one animal also showed tremors. Lethargy was observed in animals dosed at 300 and 200 mg/kg bw. All animals recovered within one day.

Animals dosed at 100 mg/kg bw did not show any signs of toxicity. Therefore, 100 mg/kg bw was selected as an appropriate dose for the micronucleus test.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
I, II, III (Vehicle controls)	5/sex	0	24, 48, 72
IV	5/sex	100	24
V	5/sex	100	48
VI	5/sex	100	72
VII (Positive control)	5/sex	50 (CP)	48

CP = cyclophosphamide

RESULTS

Doses Producing Toxicity	200, 300, 500 mg/kg bw
Genotoxic Effects	Negative.
Remarks – Results	No increase in the frequency of micronuclei was observed in all dosed groups at any sampling time.

CONCLUSION The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test.

TEST FACILITY RCC Notox (1990q)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
EEC Test Method C.6: Closed Bottle Test.

Inoculum	Filtered secondary effluent.
Exposure Period	28 days
Auxiliary Solvent	None.
Analytical Monitoring	BOD
Remarks – Method	Test concentrations of 1 and 5 mg/L were used. Each test included parallel series for the determination of oxygen depletion, with and without inoculum and positive control sodium acetate at 2 mg/L. All bottles were incubated in the dark during the test period. The oxygen concentration was determined in duplicate using oxygen electrode on days 0, 5, 15 and 28.

RESULTS

Test substance			*Sodium acetate*	
Day	*% degradation*		*Day*	*% degradation*
	1 mg/L	4.8 mg/L		
5	8	1	5	92
15	2	1	15	92
28	13	6	28	104

Remarks – Results After 28 days of incubation, biodegradation at 1 mg/L and 4.8 mg/L of the notified chemical reached 13% and 6%, respectively. The control substance was degraded by more than 60% within 5 days, thus satisfying

	the requirement that the reference substance had to attain >60% degradation, confirming the validity of the study.
CONCLUSION	The notified chemical cannot be classed as ready biodegradable.
TEST FACILITY	RCC Notox (1990r)

8.1.2. Bioaccumulation

No bioaccumulation study was conducted. In view of the negative log P_{ow} and high water solubility, the bioaccumulation potential is considered to be low (Connell, 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static
Species	*Cyprinus carpio*
Exposure Period	96 hours
Auxiliary Solvent	None.
Water Hardness	11.8°DH
Analytical Monitoring	Analysis of the test preparations showed concentrations remaining steady throughout the exposure period.
Remarks – Method	Because no toxicity was observed in the range-finding test, the final study was a limit test. In this limit test 3 groups of 10 fish were exposed for 96 h in a static system to the maximum concentration of 1000 mg/L and ten fish were exposed to untreated medium. There was no feeding from 24 h before the test and during the test period. Mortality was recorded at 3.5, 24, 48, 72 and 96 h following the start of exposure. Duplicate samples were taken from the vessels containing 0 and 1000 mg/L at time (t) = 0 and 96 h. to determine the stability of the test substance under test conditions. A reference test using pentachlorophenol was also performed to check the sensitivity of the test system.
RESULTS	
LC50	> 1000 mg/L at 96 hours.
NOEC	1000 mg/L at 96 hours.
Remarks – Results	During 96 h of exposure no mortality of fish or any other effects were observed at the nominal concentration of 1000 mg/L. During the exposure period the actual concentration remained >80% of the nominal concentration of 1000 mg/L. The 96 h LC50 for carp exposed to the notified chemical was >1000 mg/L.
CONCLUSION	The notified chemical is not toxic to *Cyprinus carpio* (Mensink *et al*., 1995).
TEST FACILITY	RCC Notox (1990s)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species	*Daphnia magna*
Exposure Period	48 hours

Auxiliary Solvent	None.
Water Hardness	11.8°DH
Analytical Monitoring	Test substance stated to be stable for 96 hours in water.
Remarks – Method	The static *Daphnia* bioassay was conducted in a 250 mL glass beaker. The lighting was maintained on a 16-h daylight photoperiod. All test organisms were observed once every 24 h for mortality and immobility. 20 daphnia were used for each test concentrations of 0, 1, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100 mg/L. Duplicate test of 10 daphnia was used for each concentration. A reference test using potassium dichromate was also used in a 48 h acute toxicity study. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test period and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*	*per replicate*	*24 h**	*48 h**
0		10	0, 0	0
1.0		"	0, 0	0
1.8		"	1, 0	1, 0
3.2		"	0, 0	1, 0
5.6		"	0, 5	0, 1
10		"	0, 1	0, 1
18		"	5, 4	3, 2
32		"	5, 4	6, 7
56		"	3, 1	7, 7
100		"	3, 4	10, 10

* At least some of the organisms appeared to be immobile because they stuck to the yellow coloured particles present in the medium and to each other. The score at 48 hours was taken after organisms were gently separated from each other and from the particles.

LC50	30.1 mg/L at 48 hours *[CI: 23.7-38.0 mg/L]*
NOEC	10 mg/L at 48 hours
Remarks – Results	All results were based on nominal concentrations. After 24 h of exposure, immobilisation of more than one daphnia was recorded at 5.6 mg/L and in the range of 18-100 mg/L. However, there was no clear concentration/response relation. Furthermore, yellow coloured particles were seen and one or more organisms appeared to be stuck to these particles and to each other. After 48 h of exposure the daphnia were scored for immobilisation before and after they were separated from each other and from the particles. The scoring before this treatment results in no clear concentration/response relation whereas the scoring after treatment showed concentration/ response relation. It is unclear why insoluble material was encountered for this very soluble dye, and the results should be viewed with caution.

CONCLUSION The notified chemical is slightly toxic to *Daphnia magna* (Mensink *et al*., 1995), probably due to a physical rather than chemical effect.

TEST FACILITY RCC Notox (1990t)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Selenastrum subspicatus*
Exposure Period	72 hours

Concentration Range	
Nominal	0-100 mg/L
Actual	99–100% of nominal
Auxiliary Solvent	ISO-medium.
Water Hardness	Not stated.
Analytical Monitoring	The concentration and stability of the test substance were verified using HPLC at 0 and 72 h.
Remarks – Method	Following a preliminary range-finding study, the green alga *Scenedesmus subspicatus* was exposed to an aqueous dispersion of the test material at a concentration of 100 mg/L (six replicate flasks) for 72 h under constant illumination and shaking at a temperature of 12ºC. Samples of algal populations were removed daily and cell concentrations determined for each control and treatment group.

RESULTS

Biomass		*Growth*	
E_bC_{50} *mg/L at 72 h*	*NOEC mg/L*	E_rC_{50} *mg/L at 24 - 48 h*	*NOEC mg/L*
> 100	$\geq$ 100	> 100	$\geq$ 100

Remarks – Results	All results were based on nominal concentrations. It was clear that neither the growth or the biomass of the green algae were affected by the presence of the test material at the nominal concentration of 100 mg/L over the 72 h exposure period.

CONCLUSION The notified chemical was very slightly toxic to algae under the conditions of the study (Mensink *et al*., 1995).

TEST FACILITY Safepharm Laboratories Limited (1997b)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

Inoculum	Sewage sludge.
Exposure Period	0.5 and 3 hours
Concentration Range	0-3200 mg/L
Nominal	
Auxiliary Solvent	none
Water Hardness	100 mg/L as $CaCO_3$/L
Analytical Monitoring	
Remarks – Method	The test material was aerated for a period of 3 h at 21ºC in the presence of activated sewage sludge with the addition of a synthetic sewage as a respiratory substrate. Based on the preliminary range finding study, the test concentrations of 32, 100, 320, 1000 and 3200 mg/L were used. The rate of respiration was determined after 30 min and 3 h contact time and compared to the data for the control and reference material 3,5-dichlorophenol.

RESULTS

IC50	> 3200 mg/L (30 min); 4000 mg/L (3 h) for test substance 11 mg/L (30 min); 8.6 mg/L for 3,5-dichlorophenol
Remarks – Results	All results were based on the nominal concentrations. The validation criteria for the control respiration rates and reference materials for EC50

	values were satisfied. The increase in toxicity of the test material after 3 h contact time is considered to be a time dependent effect and not an effect of increased solubilisation as the test material was completely soluble at the concentration tested.
CONCLUSION	The notified chemical may be considered at worst, very slightly toxic to sewage treatment bacteria.
TEST FACILITY	Safepharm Laboratories Limited (1997c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Most of the dye will be bound to paper and eventually be disposed by landfill. However, some paper will be recycled and due to the high water solubility of the dye, a large proportion will remain in the aqueous phase. Recycling may take place in a number of centres throughout Australia. The predicted concentration in sewage effluent on a nationwide basis is estimated as 0.28 μg/L.

Fate

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

9.1.2. Environment – effects assessment

In summary the aquatic toxicity data indicate:

Rainbow trout: 96 h LC50	>1000 mg/L
Daphnia magna: 48 h LC50	30.1 mg/L
Selenastrum subspicatus: 72 h E_bC50	>100 mg/L

Using the lowest LC50 of 30.1 mg/L for *Daphnia magna*, a predicted no effect concentration (PNEC) of 0.3 mg/L has been derived by dividing the LC50 value by a safety factor of 100 since toxicity data are available for all three trophic levels.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the import volume, method of packaging and low concentration in ink, release of the notified chemical to the environment is expected to be low and widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and any of the notified chemical partitioned to the supernatant water will be released to sewer.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.28/300 = 9×10^{-4} and 0.028/300 = 9×10^{-5}, for freshwater and marine water, respectively. This value is significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Office workers and customer service engineers may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, and during repair maintenance and cleaning of ink jet printers. Customer service engineers may potentially come in contact with the notified chemical more often than office workers. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Customer service engineers often wear cotton disposable gloves. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

Exposure may occur upon handling printed matter. However, very little printing ink is used per sheet of paper and it would not be separately available for exposure or dermal uptake as it is

fused and fixed to the printed surface.

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

9.2.2. Public health – exposure assessment

The printing ink will be available for use in home printers. The public will have dermal exposure to the notified chemical in the printing ink when inserting or removing a damaged cartridge and clearing paper jams. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from dermal exposure. The cartridge design also prevents leakage of ink.

Public exposure will also occur by dermal contact with printed media treated with ink containing <5 % notified chemical.

9.2.3. Human health - effects assessment

In rats, the notified chemical was toxic by oral route but of low toxicity by dermal route. Sixty percent (combined sexes) of animals treated orally with 100 mg/kg bw (the lowest dose tested), died; all deaths were within 24 hours of dosing except for one female found dead on day 4. Signs of oral toxicity include convulsions, lethargy, ataxia and piloerection. The notified chemical is classified as 'toxic if swallowed' on the basis of its acute oral toxicity. Acute inhalation toxicity study was not performed.

In rabbits, the notified chemical was not a skin irritant but it was a slight eye irritant. Slight redness of the conjuctiva persisted up to 72 hours after treatment. There was no evidence of skin sensitisation in a non-adjuvant study in guinea pigs.

In a 28-day oral repeat dose toxicity study in rats, microscopic examination revealed slight necrosis of the proximal tubules in high dose animals and very slight tubular necrosis or tubular basophilia in mid dose animals. Salivation and regurgitation was also observed, which may be due to the pharmacologic effect of the notified chemical as a ganglion-stimulating drug. Hence, low concentration of the notified chemical could activate the smooth muscle control and glandular secretion. Given the effects observed in the kidneys, the no observed effect level (NOEL) was established as 1 mg/kg bw/day (the lowest dose tested). The maximum dose tested was 50% of the dose which produced 60% mortality in acute oral toxicity testing, and it is probable that the observed effects at 10 and 50 mg/kg bw are sub-lethal acute effects.

The notified chemical showed negative results in the bacterial mutation assay, *in vitro* chromosomal aberration test and *in vivo* bone marrow micronucleus test in the absence and presence of metabolic activation (S9). The results indicate that the notified chemical was neither mutagenic nor genotoxic under the conditions of the studies.

On the basis of the data supplied, the notified chemical would be classified as a toxic (T) substance under the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC, 1999) and warrants the risk phrase: R25 – Toxic if swallowed.

9.2.4. Occupational health and safety – risk characterisation

The loading and removal of a cartridge into or from its containment area in a printer can be readily accomplished without any contact with ink. Skin contact with the ink may occur if an attempt is made to insert or remove a damaged cartridge or to correct a paper-jam.

The cartridges are not refilled. Spent cartridges contain on average <10% of remaining ink. The remaining ink is contained within the cartridge and cannot be removed without breaking the cartridge. Ink on paper will be bound to the paper and is unlikely to be transferable to a person's skin.

Overall, the risk of adverse effects arising from exposure to the notified chemical is low due to the low potential for exposure and low concentration of notified chemical in the printing ink.

Although the notified chemical is toxic via the oral route, ingestion of the notified chemical is very unlikely when used as a component of printing inks.

Based on the expected low exposures, the health risk posed to office workers, and customer service engineers by the notified chemical is very low. In addition, the occupational health risk to waterside, warehouse and transport workers is negligible, considering the small quantities in individual ink cartridges and the low hazard presented by the chemical.

9.2.5. Public health – risk characterisation

Given that the manner of exposure for the public is similar to that for office workers performing the same tasks, the risk from public exposure to the notified chemical is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are: R25 – Toxic if swallowed.

According to the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals, the notified chemical is categorised as Acute Toxicity Category 3. The following labelling requirements are applicable to the notified chemical:

Symbol: Skull and crossbones
Signal word: Danger
Hazard statement: Toxic if swallowed

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:
The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as a component of printing inks.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R25 – Toxic if swallowed

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥25%: R25 – Toxic if swallowed
  - 3%≤conc <25%: R22 – Harmful if swallowed.

CONTROL MEASURES
Occupational Health and Safety

No special precautions are required for the notified chemical when used at low quantities as a component of ink cartridges for printers. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed for use of printing inks containing the notified chemical:

- Avoid contact with skin.
- Printers should be located in well-ventilated areas.
- Service personnel should wear cotton or disposable gloves when replenishing spent ink cartridges and servicing printers.

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

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

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

Environment

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

Disposal

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

Emergency procedures

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

12.1. Secondary notification

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

(1) Under 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.

No additional secondary notification conditions are stipulated.

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