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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Yellow Dye 2

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FULL PUBLIC REPORT

Yellow Dye 2

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd (ABN 74 004 394 763)
31-41 Joseph Street
Blackburn Victoria 3130

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity;
Impurities;
Spectral data;
Percentage of dye in ink product;
Exact import volume; and
Specific use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour pressure;
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 2

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 <10% notified chemical.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<0.1	<0.1	<0.1	<0.1	<0.1

USE **Non-Confidential**
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 Victoria 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 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 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 > 300°C

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Melting point could not be determined due to auto decomposition, which occurs below the melting temperature.
TEST FACILITY	SRI International (1991a).

Density 1256 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 graduated cylinder instead of a narrow-necked pycnometer due to the large flake size of the dye, with n-hexane, as the reference solvent.
TEST FACILITY	SRI International (1991a)

Vapour Pressure Not determined

Remarks	The notified chemical is a solid salt with high molecular weight and a melting point of >300 °C. Therefore, the vapour pressure is expected to be low.

Water Solubility 423 g/L at 25°C

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

Remarks A preliminary test was conducted to estimate the mass of the test substance required to saturate a given volume of water. On the basis of the preliminary test, a definitive test was conducted by mixing 2 g of the test substance in 2 mL of water in each of the three test tubes. The tubes were shaken and then placed in a water bath at 30°C. After 24 h one tube was removed and incubated at 25°C in a second water bath for 24 h. This was repeated for the remaining tubes after 48 and 72 h. After incubation was completed the tubes were centrifuged. An aliquot was taken and analysed by HPLC.

The result indicates that the test substance was readily soluble in water (Mensink et al 1995)

TEST FACILITY SRI International (1991a)

Fat Solubility 3.2 mg/100 g fat simulant at 37°C

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

Remarks Approximately 0.17 g of the notified chemical was weighed into 8 flasks and to each flask was added 25 g of liquefied fat simulant. Four flasks were incubated at 50°C and the remaining flasks were incubated at 30°C in a water bath. The flasks were then placed in a 37°C water bath and shaken periodically over a 3-h period. After shaking of the flasks, water was added to the supernatants. The mixture was centrifuged and the aqueous layers were analysed by HPLC. The fat solubility is low.

TEST FACILITY SRI International (1991a)

Hydrolysis as a Function of pH Not determined

Remarks The test substance does not contain any functional groups which can undergo hydrolysis.

Partition Coefficient (n-octanol/water) log P_{ow} at 20°C ≤ –3.3

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks A stock solution of the test substance was prepared by dissolving 56.9 mg in 250 mL of the buffered water. 20 mL of the stock solution was placed in each of the six flasks. To the flask was added 40 mL of n-octanol. The flask was shaken for 16 h at 20°C and the pH of the aqueous phase was 7. The phases were allowed to separate, and the aliquots were taken from each phase and analysed by HPLC.

The log Pow was determined to be ≤ –3.3 indicating the test substance has a poor affinity for n-octanol.

TEST FACILITY SRI International (1991a)

Adsorption/Desorption $K_{oc} = 1.17 – 3.81 \times 10^4$ at room temperature.

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

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)(x 10^4)*
Sand	0.59	6.0	2.73
Sandy clay loam	2	6.9	3.81
Sandy clay	1.4	7.4	1.17

REMARK For this study, three different soils differing in pH, clay-content, organic matter content and in cation exchange capacity were used. Prior to adsorption study the soils were equilibrated with water. During the adsorption screening test, the test substance was added to two of the equilibrated soil samples. An amount of 10 mL 0.01 M $CaCl_2$ was added to the third equilibrated soil sample. A blank sample was performed without soil using only the test substance. All vials were tumbled gently for 16 h at room temperature. The vials were centrifuged and the supernatants were

taken and weighed. The amount of adsorption to the three soils were >25%. Therefore, the desorption test was performed using the soil samples from the adsorption tests. To each soil, 10 mL 0.01 M $CaCl_2$ was added. The process was repeated as in the adsorption procedures. Between 0.7 and 3.5% desorbed.

The result indicates that the test substance is immobilised in soil as log K_{oc} = 4.07-4.58 (McCall, 1980).

TEST FACILITY Notox (1998a)

Dissociation Constant Not determined

Remarks The notified chemical contains sulfonate groups which typically have pKa values of –1.0 to 1.0. It also contains aryl amine groups which will have pKa values of 1.0 to 5.0. The notified chemical is in a salt form and will be fully dissociated in water.

Particle Size Not determined

Remarks The notified chemical will be imported as part of an aqueous solution.

Surface Tension 50 mN/m at 20°C (1% solution)

METHOD EC Directive 92/69/EEC A.5 Surface Tension (OECD TG 115).

Remarks The surface tension of the aqueous solutions of the test substance was measured with a DuNoüy tensiometer using the ring method. Test solutions of 0.1 and 1% were used in the test. The sample vessel was raised until the ring was completely immersed in the test solution. Then it was slowly lowered until the maximum force was achieved to detach the ring from the liquid surface. The time was recorded from the transfer of the solution to the measurement vessel until after each measurement repeated until a constant surface tension was obtained. Based on the determined surface tension of 50 mN/m at 1% of the test solution, the test substance is considered to be surface active at higher concentration (result at 0.1% was 62 mN/m).

TEST FACILITY SRI International (1991a)

Flash Point Not determined

Remarks The notified chemical is solid.

Flammability Limits Non-flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

TEST FACILITY SRI International (1991a)

Autoignition Temperature 360°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks Partial oxidation and pyrolysis occurred at 250 °C and combustion of the decomposition products occurred at 360°C.

TEST FACILITY SRI International (1991a)

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

TEST FACILITY RCC Notox (1998)

Oxidizing Properties Not oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).

Remarks Preliminary test only.

TEST FACILITY SRI International (1991a)

Reactivity

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

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 203 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 - adjuvant test and non-adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity – 28 days.	NOAEL = 31 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic
Genotoxicity – in vivo mouse bone marrow micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Sprague-Dawley
Vehicle Deionised water
Remarks – Method A range finding study was conducted in rats (1/sex/group) treated with single oral dose of 63, 125 or 1000 mg/kg. Both animals dosed at 1000 mg/kg died within 17 hours of dosing. All animals survived following treatment with 63 or 125 mg/kg. Based on the result, dose levels of 275, 423, 650 and 1000 mg/kg were selected for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	75	0/10
2	5/sex	116	0/10
3	5/sex	179	6/10
4	5/sex	275	6/10
5	5/sex	423	10/10
6	5/sex	650	10/10
7	5/sex	1000	10/10

LD50 203 mg/kg (Combined sexes)
222 mg/kg (Males)
184 mg/kg (Females)
Signs of Toxicity Before death animals suffered prostration, ataxia, tremors and convulsions.

Clinical signs observed in surviving animals include: prostration, ataxia, tremors, nasal discharge, thin, ruffled fur, eye exudate, hypoactive and hunched posture.
Effects in Organs No significant gross abnormalities were observed in the decedents.

	Surviving animals showed dark spotting of the kidneys in the 75, 116 and 179 mg/kg dose groups.
Remarks – Results	All surviving animals appeared normal 5 days after treatment and showed body weight gain over the period of the study.

CONCLUSION The notified chemical is toxic via the oral route.

TEST FACILITY SRI International (1991b)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical.

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

Species/Strain	Rabbit/New Zealand White.
Vehicle	Deionised water.
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	None.

LD50	> 2000 mg/kg bw
Remarks – Results	All animals survived following treatment and showed body weight gain over the period of the study. Clinical observations or signs of toxicity were not reported.

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

TEST FACILITY SRI International (1991c)

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Vehicle	Deionised water.
Observation Period	72 hours.
Type of Dressing	Occlusive
Remarks – Method	No significant protocol deviations.

RESULTS

Remarks – Results	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 SRI International (1991d)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Observation Period	72 hours.
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	0.3	0.3	0.7	3	48 hr	0
Conjunctiva: chemosis	0.3	0.7	0.3	2	48 hr	0
Conjunctiva: discharge	0	0	0	3	1 hr	0
Corneal opacity	0	0	0.3	1	24 hr	0
Iridial inflammation	0	0	0	1	1 hr	0

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

Remarks – Results: Signs of irritation including slightly opaque cornea (as a result of corneal staining by the test substance), sluggish reaction of the iris, moderate to severe redness and swelling of the conjunctiva and marked discharge from the eye were observed at 1-hour post-instillation. All animals had circumcorneal injection. One animal continued to have yellow staining of the cornea at 24-hour observation period. All signs of irritation were resolved at 72 hours after treatment.

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

TEST FACILITY: SRI International (1991e)

7.5a. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

METHOD: EC Directive 96/54/EC B.6 Skin Sensitisation – Buehler Method.

Species/Strain: Guinea pig/Dunkin-Hartley.

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
topical: 35% w/w

MAIN STUDY

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

induction phase: Induction Concentration:
topical application: 35% w/w

Signs of Irritation: None.

CHALLENGE PHASE

1st challenge: topical application: 35% w/w

Remarks – Method: During the preliminary study, exposure was for 29 hours. Induction was for 6 hours, once a week for 3 weeks. Challenge exposure was for 24 hours.

RESULTS

Remarks – Results: No mortality, and no signs of skin sensitisation and systemic toxicity were observed during the study.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical at 35% w/w.

TEST FACILITY: SRI International (1991f)

7.5b. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

METHOD	EC Directive 96/54/EC B.6 Skin Sensitisation – maximisation test.
Species/Strain	Guinea pig/Dunkin-Hartley.
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 1% topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
induction phase	Induction Concentration: intradermal injection, 1% topical application, 50%
Signs of Irritation	None.
CHALLENGE PHASE	
1st challenge	topical application: 50%
Remarks – Method	During the preliminary irritation study, animals treated at concentrations 5%, 10%, 20% and 50 %, died immediately after intradermal injection; therefore, no skin reactions could be assessed. At 2% and 5% concentrations, necrosis was observed. No mortality occurred but clinical signs, such as watery discharge from the eyes and difficulty in breathing, were observed immediately after injection, and persisted for 6.5 hours. All animals showed orange staining of the treated skin by the test substance.
RESULTS	
Remarks – Results	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	Notox B.V. (1999a)

7.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley.
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: none
Vehicle	Deionised water.
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	None
II (low dose)	5/sex	31	None
III (mid dose)	5/sex	63	None
IV (high dose)	5/sex	125	None

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Significant reductions in average body weight were observed in high dose males beginning one week after the start of treatment and the overall weight gain was an average of 37% lower than control. The lower body weight and body weight gain were accompanied by lower food consumption. Clinical signs beginning week 2 included hunched posture, abdominal distention, thin or emaciated appearance, tremors and ataxia.

High dose females had a thin appearance throughout the study but average body weights and body weight gain were not different from control. Tremors and ataxia were observed only once during the study. Both males and females exhibited excessive salivation on intubation beginning week 2.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry:
Alkaline phosphatase (ALP) was elevated in mid and high dose animals but the increase was significant only in mid-dose females. Alanine aminotransferase levels were elevated in high dose animals. Albumin decreased significantly in high dose males and in mid and high dose females and globulin increased in high and mid dose females leading to significant decreases in A/G ratio in high dose males and mid and high dose females. A slight elevation of blood urea nitrogen (BUN) was observed in low and high dose males.

Haemotology:
A significant decrease in reticulocytes was observed in high dose animals.

Effects in Organs

Mid and high dose animals exhibited decreased absolute and relative heart weights but no histopathological effects were seen.

Increased absolute and relative liver weights in treated animals were observed. No histopathological correlates were observed.

Decreased absolute and relative spleen weights in mid and high dose males had no histopathological correlates.

Sporadic histopathological changes noted in control and treated animals include liver hyperplasia, haemorrhage and necrosis of the heart and kidney cell infiltration.

Remarks – Results
The reduced average body weights, body weight gain and food consumption in high dose males is indicative of severe chemical intoxication. The toxic effects of the test substance observed in high dose males and to a lesser extent to high dose females are associated with the initial stimulatory effect of this class of compounds in the gut.

The changes in clinical chemistry parameters and liver weights correlated with liver adaptive response to the test substance. Liver hyperplasia is reported to be the result from the greater demands of the liver to handle high doses of xenobiotics. In addition, some disruption of the cellular pumps and membranes may also be responsible for the increased in transaminases and ALP.

Decrease in reticulocyte count is often related to renal failure when production of erythropoietin is impaired. The changes in BUN are also possibly related to kidney effects. However, the significance of the decrease in reticulocyte count found in high dose-animals and BUN changes is unknown, given that no other parameters suggestive of renal failure were present.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 31 mg/kg bw/day in this study, based on the clinical chemistry and haematological effects observed in higher doses and the slight elevation of BUN in low and high dose males.

TEST FACILITY SRI International (1991g)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical.

METHOD EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Pre incubation Procedure as Modified by Prival and Mitchell (Reductive assay).

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	S9 fraction from uninduced livers of male Syrian Golden Hamsters.
Concentration Range in Main Test	a) With metabolic activation: 10 - 5000 µg/plate. b) Without metabolic activation: 10 - 5000 µg/plate.
Vehicle	Deionised water.
Remarks – Method	The study was conducted using the reductive modification to the pre-incubation assay in which the bacteria, the modified metabolic activation system (30% hamster liver S9 and reductive co-factors) or buffer, and the test article are allowed to incubate at 30°C for 30 min prior to the addition of top agar.

RESULTS

Remarks – Results	Except for a single non-reproducible observation (near doubling of control) for TA1538 in the absence of modified metabolic activation, 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 controls induced marked increases in the number of revertants, indicating that the test system responded appropriately.

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

TEST FACILITY SRI International (1991h)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	Human peripheral lymphocytes.
Metabolic Activation System	Aroclor-1254 induced rat liver S9 homogenate.
Vehicle	F10 complete culture medium.
Remarks – Method	Dose levels for the first cytogenetic assay (Test 1) were determined from a dose range finding test. Dose levels for the second cytogenetic assay (Test 2) were determined from the data of the range finding test and the first cytogenetic assay. All doses were used for scoring of chromosome aberrations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 1000, 3330, 5000	3 hr	24 hr
Test 2	0, 1000, 3330, 5000	24 hr	24 hr
	0, 1000, 3330, 5000	48 hr	48 hr
Present			
Test 1	0, 1000, 3330, 5000	3 hr	24 hr

Test 2	0, 1000, 3330, 5000	3 hr	48 hr

RESULTS

Remarks – Results	No statistically significant increase in the frequency of cells with chromosomal aberrations either in the absence or presence of metabolic activation. A significant reduction in mitotic index (below 50%) was seen for the tested doses in the absence of metabolic activation for treatment times of 24 hour and above. Appropriate positive controls induced marked increases in the number of aberrant cells, indicating that the test system responded appropriately.
CONCLUSION	The notified chemical was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.
TEST FACILITY	Notox B.V (1999b)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical.
METHOD	Conforms to EC Directive 2000/32/EC B.11 Mutagenicity - In vivo Mammalian Bone-Marrow Chromosome Aberration Test.
Species/Strain	Mouse/Swiss-Webster.
Route of Administration	Oral – gavage.
Vehicle	Deionised water.
Remarks – Method	In a range finding study, 3 animals/sex/group were treated orally with 0, 60, 125, 250, 500 and 1000 mg/kg bw test substance. All animals dosed at 1000 mg/kg and four animals (3 females and 1 male) dosed at 500 mg/kg died after the treatment. There were no clinical findings reported on surviving animals. The doses for the main study were selected based on the incidence of mortality from the range finding study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
I (Vehicle control)	5/sex	0	24, 48, 72
II	5/sex	90	24, 48, 72
III	5/sex	175	24, 48, 72
IV	5/sex	350	24, 48, 72
V (Positive control)	15 males	300 (Urethane)	24, 48, 72

RESULTS

Doses Producing Toxicity	1000 and 500 mg/kg
Genotoxic Effects	Negative.
Remarks – Results	There were no remarkable body weight changes during the study. No statistically significant increase in the frequency of micronuclei was observed in all dosed groups at any sampling time. Appropriate positive controls induced marked increases in micronuclei, indicating that the test system responded appropriately.
CONCLUSION	The notified chemical was not clastogenic in this in vivo mouse micronucleus assay under the conditions of the test.
TEST FACILITY	SRI International (1991i)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	EEC Test Method C.6: Closed Bottle Test.
Inoculum	Secondary effluent from composite sampler at the Columbia Municipal Wastewater Treatment Plant, filtered through coarse filter paper and aerated for 1 hour at room temperature until used.
Exposure Period	28 days.
Auxiliary Solvent	None.
Analytical Monitoring	BOD
Remarks – Method	A concentration of 2.19 mg/L for the notified chemical was used in the test. Each test included parallel series for the determination of oxygen depletion, without inoculum, in the presence of inoculum and with the positive control aniline at 2 mg/L. Duplicate bottles were prepared and analysed for dissolved oxygen on days 0, 5, 15 and 28 for blank control, test substance and reference substance while a single bottle was analysed for inoculum control.

RESULTS

Test substance		*Aniline reference substance*	
Day	*% degradation*	*Day*	*% degradation*
5	2.0	5	4.1
15	0	15	89
28	0	28	83

Remarks – Results	After 28 days of incubation, biodegradation at 2.19 mg/L of the notified chemical was found to be nil. The reference substance was degraded by more than 60% within 15 days, thus satisfying the requirement that the reference substance had to attain >60% degradation, and confirming the validity of the study. It is noted that the oxygen depletion for both the uninoculated blank and the inoculated blank were above the values recommended by the guideline. The author indicates that these values do not significantly affect the overall outcome of the study.
CONCLUSION	The notified chemical cannot be classed as ready biodegradable.
TEST FACILITY	Analytical Biochemistry Laboratories (1991a)

8.1.2. Bioaccumulation

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

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish-static.
Species	*Oncorhynchus mykiss* (rainbow trout).
Exposure Period	96 hours
Auxiliary Solvent	None.
Water Hardness	40-48 mg $CaCO_3$/L

Analytical Monitoring	The test preparations were monitored by spectrophotometry.
Remarks – Method	Based on the result of the preliminary testing, nominal concentrations of 56, 100, 180 320 and 560 mg/L were used for the definitive test. For each concentration, 10 fish were tested, in duplicate. All test organisms were observed once every 24 h for mortality and abnormal sublethal effects such as surfacing, loss of equilibrium, dark discolouration, laboured respiration, fish on the bottom of test chamber and or quiescence. The study area was maintained on a 16 h daylight photoperiod. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	20		0	0	0	0
56	48	20		0	0	0	0
100	95	20		0	0	0	0
180	180	20		0	0	0	0
320	300	20		0	0	1	2
560	510	20		0	1	12	15

LC50 420 mg/L at 96 hours *(CI: 370-490 mg/L)*
NOEC 48 mg/L at 96 hours
Remarks – Results The test concentrations of the notified chemical were determined from samples collected at 0 and 96 h. The mean test concentrations were determined to be 48, 95, 180, 300 and 510 mg/L. The abnormal effects noted above were increasingly observed above 95 mg/L. The results indicate that a 96 h no-observed effect concentration could be estimated as 48 mg/L.

CONCLUSION The notified chemical is very slightly toxic to *Oncorhynchus mykiss* (rainbow trout).

TEST FACILITY Analytical Biochemistry Laboratories (1991b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent None.
Water Hardness 184 mg $CaCO_3$/L
Analytical Monitoring UV-visible Spectrophotometry.

Remarks – Method Based on the results of the preliminary testing, nominal concentrations of 1.7, 3.3, 7.5, 15, 30 and 60 mg/L were used for the definitive test. For each concentration, 10 daphnia were tested, in duplicate. All test organisms were observed once every 24 h and 48 h for mortality and abnormal sublethal effects such as surfacing, daphnias trailing extraneous material, quiescence and/or daphnias tending to the bottom of the test chambers. The study area was maintained on a 16 h daylight photoperiod with 30 minute dawn dusk transition periods. Water quality parameters of temperature, dissolved oxygen and pH were measured throughout the test and were within acceptable limits.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*	*per replicate*	*24 h*	*48 h*
0	0	10	0, 0	0, 0
1.7	1.8	10	0, 0	0, 0
3.3	3.2	10	0, 0	0, 0
7.5	7.2	10	0, 0	0, 0
15	15	10	0, 0	3, 0
30	31	10	0, 0	5, 5
60	59	10	3, 1	8, 8

LC50	32 mg/L at 48 hours (CI: 25-42 mg/L)
NOEC	3.2 mg/L at 48 hours
Remarks – Results	The test concentrations of the notified chemical were quantitated from samples collected at 0 and 48 h. All results were based on the measured concentrations of 48, 95, 180, 300 and 510 mg/L. As the sub-lethal effects described above were increasingly observed from 7.2 mg/L, the 96 h no-observed effect concentration was determined to be 3.2 mg/L.
CONCLUSION	The notified chemical is slightly toxic to *Daphnia magna*.
TEST FACILITY	Analytical Biochemistry Laboratories (1991c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	
Nominal	0-100 mg/L
Actual	0-100 mg/L
Auxiliary Solvent	ISO-medium
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	UV-visible Spectrophotometry.
Remarks – Method	The test began with two range finding tests and an additional indirect test which was performed to examine if the test substance could indirectly inhibit the growth of the green algae by light absorption as a result of the colour of the test solutions. The test was then conducted by exposing growing algal cultures to the test substance concentrations varying from 1.0-100 mg/L for a period of 72 h. The test was subsequently repeated by exposing algal suspensions indirectly to the same concentration range to examine the effect of light absorption by the colour of the test solutions. At the beginning of the test cells were counted by microscope using a counting chamber. Thereafter cell densities were determined by using UV-visible spectrometry. EC_{50} calculation was performed by linear regression analysis between growth rates caused by direct exposure as a % of those caused by indirect exposures versus the logarithm of the nominal concentrations. All test conditions were within the range of acceptability.

RESULTS

Growth	
ErC50	*NOEC*
mg/L at 0 - 72 h	*mg/L*
17 - 29	6

Remarks – Results	The notified chemical affected the growth of the algal species by absorption of wavelengths necessary for algal growth but at concentrations above 18 mg/L an increasing and direct toxic effect was observed. Nominal concentrations ranged between 0 and 100 mg/L in the tests. The EC_{50} for algal growth corresponds to a nominal concentration range of 19 to 45 mg/L. The actual range was based on a recovery of 60% test substance at 10 mg/L and 100% at 100 mg/L corresponding to 0-72 h EC_{50} ranging from 17-29 mg/L. The NOEC for the effect on cell growth is 10 mg/L, corresponding with an average exposure

concentration of 6 mg/L.

CONCLUSION	The notified chemical is slightly toxic to algae.
TEST FACILITY	Notox (1998b)

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 hours
Concentration Range Nominal	0-133 mg/L (approximately 100 mg/L active ingredient)
Remarks – Method	The test method is a rapid screening method whereby the test material was aerated for a period of 30 min at 20ºC in the presence of activated sewage sludge. A concentration of approximately 100 mg/L for test substance in duplicate was used in the test. The rate of respiration was determined after 30 min and compared to the data for the control and reference material 3,5-dichlorophenol at concentrations of 3.2, 10 and 32 mg/L
RESULTS	
IC50	> 100 mg/L
NOEC	100 mg/L (a.i.)
Remarks – Results	All results were based on the nominal concentrations. The validation criteria for the control and reference material for EC_{50} values were satisfied. No significant inhibition of the respiration rate was recorded at 100 mg/L of the notified chemical.
CONCLUSION	The notified chemical was not toxic to waste-water bacteria at a concentration of 100 mg/L.
TEST FACILITY	Notox (1999c)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

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 greater 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 0.014 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 as indicated in its log K_{oc} of 4.07-4.58.

9.1.2. Environment – effects assessment

In summary the aquatic toxicity data indicate:

Rainbow trout (*Oncorhynchus mykiss)*: 96 h LC50	420 mg/L
Daphnia magna: 48 h LC50	32 mg/L
Algae *(Selenastrum capricornutum)*: 72 h E_bC50	17-29 mg/L

Using the lowest LC50 of 17 mg/L for algae, a predicted no effect concentration (PNEC) of 0.17 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 8.2×10^{-5} (0.014/170) and 8.2×10^{-6} (0.0014/170), for freshwater and marine water, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment. This value is expected to be much lower given that not all paper to which the ink is applied will be recycled thus limiting the exposure of the notified chemical to sewer.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

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 <10% 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. Signs of oral toxicity include prostration, ataxia, tremors and convulsions. The acute oral LD_{50} in rats was estimated to be 203 mg/kg for combined sexes (95% confidence limits of 156 to 258 mg/kg; slope = 2.31). 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. Signs of irritation including opaque cornea, sluggish iris, moderate to severe redness and swelling of conjunctiva and discharge from the eyes were observed. Irritation resolved at 72 hours after treatment. There was no evidence of skin sensitisation in an adjuvant and non-adjuvant studies in guinea pigs.

In a 28-day oral repeat dose toxicity study in rats, reduced average body weights, body weight gain and food consumption in high dose males, which is indicative of severe chemical intoxication were observed. The toxic effects of the test substance observed in high dose males and to a lesser extent to high dose females are associated with the initial stimulatory effect of this class of compounds in the gut.

The increased in clinical chemistry parameters and liver weights correlated with liver adaptive response to the test substance. Liver hyperplasia is reported to be the result from the greater demands of the liver to handle high doses of xenobiotics. In addition, some disruption of the cellular pumps and membranes may also be responsible for the increased in transaminases and ALP.

The significance of decrease in reticulocyte count observed in high dose animals is unknown, given that no other parameters suggestive of renal failure were present

The No Observed Adverse Effect Level (NOAEL) was established as 31 mg/kg bw/day (the lowest dose tested) in this study, based on the clinical chemistry and haematological effects observed in higher doses, and the slight elevation of BUN in low and high dose males. The maximum dose tested was close to a dose which produced 60% mortality in acute oral toxicity testing, and it is likely that some of the observed effects are sublethal 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 contained within the cartridge 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.

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

Acute Toxicity Category 3
Symbol: Skull and crossbones
Signal word: Danger
Hazard statement: Toxic if swallowed

Chronic Hazards to the Aquatic Environment Category 3
Symbol: No symbol used
Signal word: No signal word
Hazard statement: Harmful to aquatic life with long lasting effects

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used as 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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