File No: LTD/1094

10 October 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Red Dye 1

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

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

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

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

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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

Director

Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Red Dye 1

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:

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)
Red 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 <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
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 20ºC and 101.3 kPa Flaky solid.

Melting Point > 300ºC

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Exact melting point cannot be determined because auto-decomposition occurs below the melting temperature.
TEST FACILITY SRI International (1991a)

Density 1385 kg/m^3 at 20ºC

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 a the reference solvent..
TEST FACILITY SRI International (1991a)

Vapour Pressure Not determined

Remarks The notified chemical is a solid salt with a melting point above 300 ºC. Therefore, the vapour pressure is expected to be low.

Water Solubility 200 g/L at 20ºC at pH 4.86

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 6 g of the test substance in 20 mL of water in each of the three test flasks. The flasks were shaken and then placed in a water bath at 30ºC. After 24 h one tube was removed and incubated at 25ºC in a second water bath for 24 h. This was repeated for the remaining tubes after 48 and 72 h at 30ºC. After incubation was completed the tubes were centrifuged and the pH of the solution was measured. An aliquot was taken and analysed by HPLC.

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

TEST FACILITY SRI International (1991a)

Fat Solubility 2.1 mg/100 g fat at 37°C

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

Remarks Approximately 0.18g of the notified chemical was weighed into 8 flasks. 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 for 3 h. The flasks were then placed in a 37°C water bath and shaken periodically over a 3-h period, after which they were allowed to stand at 37°C for 24 h to allow particles to settle. Water was then added to the supernatants. The mixture was centrifuged and the aqueous layers were analysed by HPLC. The fat solubility was found to be low.

TEST FACILITY SRI International (1991a)

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)*	*t½ at 25°C*
4	25	> 1 yr
7	25	> 1 yr
9	25	> 1 yr

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 120 h. The concentration of the test solution was determined using HPLC. No significant hydrolysis was observed in the first preliminary test over 5 days. A second preliminary test using a lower concentration of the test substance was conducted as a consequence of the spread of the results in the first preliminary test. The test substance was shown to be hydrolytically stable within the environmental pH range.

TEST FACILITY Notox (1998a)

Partition Coefficient (n-octanol/water) log Pow at 20ºC = -1.41

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

Remarks A stock solution of the test substance was prepared by dissolving 48.6 mg in 250 mL of the buffered water. 20 mL of the stock solution was placed in each of the six flasks. To the flasks was added a measured volume of n-octanol. The flasks were shaken for 16 h at 20ºC 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 ≤-1.4 indicating the test substance has a poor affinity for n-octanol.

TEST FACILITY SRI International (1991a)

Adsorption/Desorption Log K_{oc} = 2.31 - 3.31(approx) at 20°C.

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

Soil Type	*Organic Carbon Content (%)*	*pH*	*logKoc (mL/g)*
Sand	0.59	6.0	2.31
Sandy clay loam	2.0	6.9	3.01
Sandy clay	1.4	7.4	3.31

Remarks 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 two of the 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 24.7 and 29.2% desorbed.

The result indicates that the test substance is of medium to low mobility in soil as log Koc = 2.31 to 3.31 (McCall *et al* 1980).

TEST FACILITY Notox (1997a)

Dissociation Constant Not determined

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

Particle Size Not applicable

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

Surface Tension 67.9 mN/m at 20°C (1% solution)

METHOD EC Directive 92/69/EEC A.5 Surface Tension.

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 immediately after each measurement, which was repeated until a constant surface tension was obtained. Based on the determined surface tensions of 73.2 mN/m and 64.2 mN/m at 0.1 and 1% of the test solution, respectively, the test substance is considered not to be surface active.

TEST FACILITY SRI International (1991a)

Flash Point >93.3°C (ink formulation)

Remarks Test report not provided.

Flammability Limits Non-flammable.

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

Remarks The test substance could not be ignited either by flame or glowing nichrome wire.

TEST FACILITY SRI International (1991a)

Autoignition Temperature 270°C (approx.)

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Compatible with the results for melting point and flammability.
TEST FACILITY SRI International (1991a)

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY RCC Notox (1991)

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 > 5000 mg/kg bw	low toxicity
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/non-adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOAEL = 125 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic
Genotoxicity – in vivo mouse micronucleus	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/Sprague-Dawley.
Vehicle Deionised water. Dose volume 40 mL/kg
Remarks-Method A range finding study was conducted in rats (1/sex/group) with an oral dose of 100, 1000 or 5000 mg/kg bw. No mortality was observed following treatment; therefore, 5000 mg/kg bw was the dose selected for the oral acute toxicity test. Animals treated with 5000 mg/kg had ataxia, hunched posture, hypoactivity, ruffled fur and discoloured (purple) urine and faeces.
The dosing regimen in the main test comprised of two equal portions, 5.3 hr apart

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	5000	None.

LD50 > 5000 mg/kg bw

Signs of Toxicity	Slight hypoactivity in all animals on days 1 and 2. Purple coloured faeces and urine in all animals on days 2 to 5. No effect on body weight gain was seen.
Effects in Organs	No macroscopic abnormalities seen at necropsy.
Remarks – Results	All treated rats appeared normal, and discolouration or urine and faeces disappeared throughout the remainder of the 2-week study.

CONCLUSION The notified chemical is of low toxicity 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
Signs of Toxicity - Local	No signs of irritation were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed.
Effects in Organs	No macroscopic abnormalities seen at necropsy.
Remarks-Result	All treated rats appeared normal. No effect of body weight gain was seen.

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-Method	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	0.3	2	24 hr	0
Conjunctiva: chemosis	0.3	0	0.3	2	24 hr	0
Conjunctiva: discharge	0	0	0.3	1	48 hr	0
Corneal opacity	0	0	0	2	1 hr	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-Result

At 1 hr after treatment, the cornea of all three animals was opaque and stained purple. Corneal opacity and staining resolved by 24 hours. Irritation of the conjunctiva was also observed, which include redness, swelling, partial eversion of the eyelids and discharge from the eyes.

No irritation was evident in all animals 72 hours after treatment.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

SRI International (1991e)

7.6.1 Skin sensitisation – Buehler Test

TEST SUBSTANCE

Notified chemical.

METHOD

EC Directive 96/54/EC B.6 Skin Sensitisation - Buehler.

Species/Strain

Guinea pig/Dunkin-Hartley.

PRELIMINARY STUDY

Maximum Non-irritating Concentration:
topical: 20%

MAIN STUDY

Number of Animals

Test Group: 10 Control Group: 10

induction phase

Induction Concentration:
topical application: 20% w/w

Signs of Irritation

None.

CHALLENGE PHASE

1st challenge

topical application: 20% w/w

Remarks-Method

In the preliminary study, guinea pigs (1/sex/group) were treated with 10 and 20% test substance for a 29-hour exposure period. In the main study, induction was for 6 hours, once a week for 3 weeks. Challenge exposure was extended for 24 hours to increase the sensitivity of the test.

Modifications in the wrapping methods were made to increase the motility and comfort of the animals.

Animals were inadvertently not observed for a two-day period; however, this deviation from the protocol is not expected to affect the results of the study.
A simultaneous positive control group treated with dinitrochlorobenzene was used.

RESULTS

Animal	*Challenge Concentration (% w/w)*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*
Test Group	20	2/10	0/10
Control Group	20	2/10	0/10

Remarks – Results	No irritation reactions were observed in all animals in the preliminary study. At 24-hours after challenge, very faint to moderate erythema was observed in both test and control groups. All irritation effects were cleared by 48 hours after the challenge. The skin reactions are considered skin irritation response rather than sensitisation response since the skin reaction disappeared after 24 hours. No mortality and systemic toxicity were observed during the study.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	SRI International (1991f)

7.6.2 Skin sensitisation – Maximisation Test

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 406 Skin Sensitisation - Maximisation Test . EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation Test.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% topical: 20%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
induction phase	Induction Concentration: intradermal injection, 10% topical application, 20%
Signs of Irritation	Two test animals showed necrosis at the injection sites possibly attributable to the notified chemical.
CHALLENGE PHASE	
1st challenge	topical application: 20%
Remarks-Method	A preliminary irritation study was conducted to determine the appropriate test substance concentration for the main study. A 20% test substance concentration was the highest concentration that could technically be injected. At 24 hours after injection, erythema was seen on animals treated with 10 and 20% test substance. Necrosis was evident in animals injected with 20% after 48 hours. Purple staining of the treated skin by the test substance of all animals was seen. No signs of irritation were evident on animals injected with 2 and 5% test concentration.
RESULTS	
Remarks – Results	During the main study, no signs of skin sensitisation and systemic toxicity were observed, and no mortality occurred. No skin reactions were seen after challenge. Body weights and body weight gain of treated animals were comparable to the controls over the study period. Purple staining of the treated skin by the test substance was seen in all animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical at 20% w/w.
TEST FACILITY	Notox B.V. (1999a)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	
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	125	None
III (mid dose)	5/sex	354	None
IV (high dose)	5/sex	1000	None

Mortality and Time to Death

There were no unscheduled deaths during the study.

Clinical Observations

Dose-dependant colouration of fur, feet, tail, urine and faeces in all treated groups. Reduction in average weekly body weights and lower weight gain were observed in mid and high dose males. One male in the high dose group was slightly hunched in the second week of treatment.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical chemistry: Alanine aminotransferase (ALT) was significantly elevated in mid and high dose males and in high dose females. Increases in aspartate aminotransferase (AST) were seen in mid and high dose males, but these were not statistically significant. Lactate dehydrogenase (LDH) was significantly elevated in high dose males. Globulin was significantly elevated in mid and high dose females and the A/G ratios were consequently decreased in the same female groups; a similar but not statistically significant effect was seen in high dose males.

Haematology: Small significant increases in mean corpuscular haemoglobin concentration (MCHC) occurred in mid and high dose animals.

Effects in Organs

A significant decrease in absolute liver weight and liver:brain weight ratio was observed in high dose males. A significant increase in absolute liver weight, liver:body weight and liver:brain weight ratios were observed in high dose females.
At necropsy, the contents or tissue of the gastrointestinal tract (GIT) of all treated rats were discoloured pink/purple. Splenic abnormalities (enlarged, firm, rough surface, ectopic splenic tissue or dark colouration) were seen in some mid dose males and high dose animals. Sporadic histopathological changes noted in control and treated animals include liver hyperplasia, haemorrhage and necrosis of the heart and interstitial eosin in the lungs. Absolute testes weights were decreased in mid and high dose males although the relative testes weights were similar to controls.

Remarks – Results

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. Some disruption of the cellular pumps and membranes may also be responsible for the increased in transaminases. In addition, changes in the serum levels of albumin and globulin often suggest liver involvement, although kidney effects are also caused by decreases in levels of albumin. There were no microscopic lesions found upon examination of the liver, kidney, the GIT and spleen.

Other statistically significant differences in organ to body ratios were observed. However, these differences were not considered biologically significant because their occurrence are isolated and not dose-related. Changes in testes weights appeared to be due to reduced body weights in the mid and high dose males.

Changes in MCHC have been related to hemolysis, which is usually associated with other hematologic changes such as urobilinogen in the urine, hyperaemia in the spleen and splenomegaly. However, the significance of the decrease in MCHC found in mid and high dose-animals is dubious, given than no other haematological effects were seen.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 125 mg/kg bw/day (the lowest dose tested) in this study, based on effects on clinical chemistry, haematology, body and organ weights.

TEST FACILITY	SRI International (1991g).

7.8. 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 Yahagi et al.
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System	Aroclor 1254 - induced rat liver S9 homogenate.
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 test organisms (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 bacterial growth medium. This initial step increases the likelihood that active metabolites that are short-lived or unstable, or that occur in low concentrations, will react with the genetic material of the test organisms. No substantial increase in the number of revertant colonies and no toxicity were seen in any strain either in the presence or absence of metabolic activation. At 5000 µg/plate, the colonies were hand counted because the dark colouration of the plates interfered with the automated counter. Two independent tests were performed. In the first assay, 4% S9 was used for metabolic activation; the second assay used 10% S9.

RESULTS

Remarks – Result	No substantial increase in the number of revertant colonies was seen in any strain either in the presence or absence of metabolic activation in both assays. No precipitation or cytotoxicity was observed. Appropriate positive controls induced marked increases in the number of revertant colonies, 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).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Cell Type/Cell Line	Peripheral human 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.

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

All cultures selected for metaphase analysis.

RESULTS

Remarks-Result — No statistically significant increase in the frequency of cells with chromosomal aberrations either in the absence or presence of metabolic activation. No evidence of cytotoxicity was observed.

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).

7.10. Genotoxicity – in vivo

TEST SUBSTANCE — Notified chemical.

METHOD — 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	No significant deviations. The dose levels for the main study were selected from a dose range finding study.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time Hours*
1	5/sex	0	24, 48, 72 hours

2	5/sex	1200	24, 48, 72 hours
3	5/sex	2500	24, 48, 72 hours
4	5/sex	5000	24, 48, 72 hours
5	15 males	300 mg/kg Urethane	24, 48, 72 hours

RESULTS

Doses Producing Toxicity	None.
Genotoxic Effects	Negative.
Remarks-Result	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 micronucleus 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 2.0 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	4.9	5	2.1
15	12	15	9.1
28	12	28	62

Remarks - Results	After 28 days of incubation, biodegradation at 2.0 mg/L of the notified chemical was found to be 12%. The reference substance was degraded by more than 60% by day 28, thus satisfying the requirement that the reference substance had to attain >60% degradation, and confirming the validity of the study.
CONCLUSION	The notified chemical cannot be classed as ready biodegradable.

TEST FACILITY	Analytical Bio-chemistry Laboratories Ltd (1991a)

8.1.2. Bioaccumulation

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

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	*Oncorhynchus mykiss* (rainbow trout).
Exposure Period	96 hours.
Auxiliary Solvent	None.
Water Hardness	40-48 mg $CaCO_3$/L
Analytical Monitoring	Analysis of the test preparations by spectrophotometry showed concentrations remaining steady throughout the exposure period.
Remarks - Method	Based on the result of the preliminary testing, nominal concentrations of 18, 32, 57, 100 and 180 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 dark discolouration and rapid respiration. 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	
LC50	> 180 mg/L at 96 hours.
NOEC	18 mg/L at 96 hours.
Remarks – Results	All results were based on the measured concentrations of the test substance. The 24, 48, 72 and 96 h LC50 for the test substance were >180 mg/L. The test solution was a dark red colour that increased in intensity as the test concentration increased. A white flocculent precipitate was noted at the bottom of the test chambers at 72 and 96 h. Abnormal effects of dark discolouration and rapid respiration were observed in the 32, 57, 100 and 180 mg/L test concentration at 24 and 48 h of exposure. No abnormal effects were observed in any concentration at 72 and 96 h. No mortality was observed in any control or test concentrations during the test. The 96 h NOEC was estimated to be 18 mg/L based on the lack of mortality and sub-lethal effects.
CONCLUSION	The notified chemical is very slightly toxic to *Oncorhynchus mykiss*
TEST FACILITY	Analytical Bio-chemistry Laboratories Ltd. (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	160 mg $CaCO_3$/L
Analytical Monitoring	Analysis of the test preparations by spectrophotometry showed

	concentrations remaining steady throughout the exposure period.
Remarks – Method	Based on the results of the preliminary testing, nominal concentrations ranging from 63-1000 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 immobility 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 [acute]*	*48 h [acute]*
0	0	10	0, 0	0, 0
63	62.3	10	0, 0	0, 0
125	124	10	0, 0	0, 0
250	248	10	0, 0	0, 0
500	496	10	0, 0	10, 10
1000	998	10	4, 5	10, 10

LC50 351 mg/L at 48 hours
NOEC 124 mg/L at 48 hours
Remarks – Results The test concentrations of the notified chemical were quantitated and validated from samples collected at 0 and 48 h. All results were based on the measured concentrations of test substance ranging 62.3 to 998 mg/L. Immobility and abnormal effects of daphnia tending to the bottom of the test vessels and surfacing in the test vessels were observed in the test concentrations of 248, 496 and 998 mg/L. As the sub-lethal effects described above were increasingly observed from 248 mg/L, the 48 h no-observed effect concentration was determined to be 124 mg/L.

CONCLUSION The notified chemical is very slightly toxic to *Daphnia magna*.

TEST FACILITY Analytical Biochemistry Laboratories Ltd (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 1.0, 2.2, 4.6, 10, 22, 46 and 100 mg/L
Auxiliary Solvent ISO-medium
Water Hardness 24 mg $CaCO_3$/L
Analytical Monitoring HPLC
Remarks – Method The test began with 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 to 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 counting chamber. Thereafter cell densities were determined by using UV-visible spectrometry. The concentrations of the test solutions were measured by HPLC and validated. At the end of the 72 h exposure, the measured concentrations had not decreased by more than 20%. A reference test using potassium dichromate was also performed to check the sensitivity of the test system. 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	
IC50	76.6 mg/L at 72 hours
NOEC	10 mg/L at 72 hours
Remarks – Results	Comparison of the data for growth inhibition with those recorded during direct exposure show that the effects of direct and indirect exposure on algal growth are comparable. The notified chemical affected the growth of the algal species by absorption of wavelengths necessary for algal growth instead of by toxic processes as measured by comparison of the effects of indirect and direct exposure.
CONCLUSION	The notified chemical is slightly toxic to the algae *Selenastrum capricornutum.*
TEST FACILITY	Notox B.V. (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	0-100 mg/L
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
Remarks – Results	All results were based on the nominal concentrations. The respiration rates for the controls were within 15% of each other. The EC_{50} of the reference material was validated. 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 B.V. (1997b)

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 0.14 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 2.31-3.31.

9.1.2. Environment – effects assessment

In summary the aquatic toxicity data indicate:

Rainbow trout (*Oncorhynchus mykiss)*: 96 h LC_{50}	>180 mg/L
Daphnia magna: 48 h LC_{50}	351 mg/L

Using the lowest LC_{50} of 180 mg/L for rainbow trout, a predicted no effect concentration (PNEC) of 0.18 mg/L has been derived by dividing the LC_{50} value by a safety factor of 1000 since toxicity data are available for two 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 (<5%), release of the notified chemical to the environment is expected to be low and widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and any of the notified chemical partitioned to the supernatant water will be released to sewer.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 7.7×10^{-4} (0.14/180) and 7.7×10^{-5} (0.014/180), 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 <5% notified chemical.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral toxicity in rats and of low dermal toxicity in rabbits. It was not irritating to skin but it was a slight eye irritant in rabbits. Eye irritation was evidenced by transient irritation of the cornea (opaque and stained purple) and conjunctiva (redness, swelling, partial eversion of the eyelids and discharge from the eyes). There was no evidence of skin sensitisation in an adjuvant and non-adjuvant studies in guinea pigs. The notified chemical was neither mutagenic in bacteria nor clastogenic in human peripheral lymphocyte and mouse bone marrow.

In a 28-day oral repeat dose toxicity study in rats, the increases in transaminases and liver weights correlated with liver adaptive response to the test substance. Liver hyperplasia was 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. The increased in the serum levels of albumin and globulin was also indicative of liver effects.

The significance of the decrease in mean corpuscular haemoglobin concentration (MCHC) found in mid and high dose animals was questionable, given that no other haematological effects were seen to indicate the possibility of haemolysis caused by the changes in MCHC. The No Observed Adverse Effect Level (NOAEL) was established as 125 mg/kg bw/day (the lowest dose tested) in this study, based on the clinical chemistry and haematological effects observed in higher doses.

On the basis of the data supplied, the notified chemical would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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 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.

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 not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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.

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

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.

13. BIBLIOGRAPHY

Analytical Bio-Chemistry Laboratories, Inc. (1991a) Determination of Ready Biodegradability of Red Dye 1 in the Closed Bottle Test. Report No. 39066. Analytical Bio-Chemistry Laboratories, Inc. Missouri.

Analytical Bio-Chemistry Laboratories, Inc. (1991b) Acute Toxicity of Red Dye 1 to Rainbow Trout (*Oncorhynchus mykiss*). Report No. 39068. Analytical Bio-Chemistry Laboratories, Inc. Missouri.

Analytical Bio-Chemistry Laboratories, Inc. (1991c) Acute Toxicity of Red Dye 1 to *Daphnia magna*. Report No. 39069. Analytical Bio-Chemistry Laboratories, Inc., Missouri.

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

McCall, P. H., Swann, R. L., Laskowski, D. A., Unger, S. M., Vrona, S. A. and Dishburger, H. J. (1980). Estimation of Chemical Mobility in Soil from Liquid Chromatographic Retention times. *Bull. Environ. Contam. Toxicol*. 24: 190-195.

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

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

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

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

Notox (1997a) Soil Adsorption/Desorption of Red Dye 1 on 3 Soils (Screening Test). Project 215606. Notox B.V., The Netherlands.

Notox (1997b) Activated Sludge Respiration Inhibition Test with Red Dye 1. Project 215742. Notox B.V., The Netherlands.

Notox (1998a) Determination of the Hydrolysis of Red Dye 1 as a Function of pH. Project 228105. Notox B.V., The Netherlands.

Notox (1998b) Fresh Water Algal Growth Inhibition Test with Red Dye 1. Project 215674. Notox B.V., The Netherlands.

Notox (1999a) Assessment of Contact Hypersensitivity to Red Dye 1 in the Albino Guinea Pig (Maximisation Test). Project 257006. Notox B.V., The Netherlands.

Notox (1999b) Evaluation of the Ability of Red Dye 1 to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes. Project 255588. Notox B.V., The Netherlands.

Notox (1999c) Activated Sludge Respiration Inhibition Test with Red Dye 1. Project 215742. Notox, B.V., The Netherlands.

RCC Notox (1991) Determination of the Explosive Properties of Red Dye 1. Project 287796. RCC Notox B.V., The Netherlands.

SRI International (1991a) Physicochemical Propteries of Red Dye 1. Report No. 1488-E11-01-90. SRI International, USA.

SRI International (1991b) Acute Oral Toxicity Study of Red Dye 1 in Rats. Study No. 1488-M09-90. SRI International, USA.

SRI International (1991c) Acute Deraml Toxicity Study of Red Dye 1 in Rabbits. Study No. 1488-M01-90. SRI International, USA.

SRI International (1991d) Primary Skin Irritation Study of Red Dye 1 in Rabbits. Study No. 1488-M03-90. SRI International, USA.

SRI International (1991e) Primary Eye Irritation Study of Red Dye 1 in Rabbits. Study No. 1488-M05-90. SRI International, USA.

SRI International (1991f) Skin Sensitisation Study of Red Dye 1 in Guinea Pigs (Buehler Topical Closed Patch Technique). Study No. 1488-M07-90. SRI International, USA.

SRI International (1991g) 28-Day Repeated Dose Toxicity Study of Red Dye 1 in Rats. Study No. 1488-M11-90. SRI International, USA.

SRI International (1991h) Salmonella/Microsome Preincubation Assay of Red Dye 1. Study No. 1488-A08-01-90. SRI International, USA.

SRI International (1991i) Measurement of Micronuclei in Bone Marrow Erythrocytes of Swiss-Webster Mice Following Treatment with Red Dye 1. Study No. 1488-C09-01-90. SRI International, USA.

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