File No STD/1093

23 April 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

FYS-108

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

FYS-108

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
EPSON Australia Pty Ltd (ABN 91 002 625 783)
3 Talavera Rd
North Ryde NSW 2113

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Identity of chemical;
Composition; and
Exact Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a function of pH;
Dissociation constant;
Flash point;
Bioaccumulation potential;
Acute inhalation toxicity; and
Induction of germ cell damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
UK (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FYS-108

3. COMPOSITION

DEGREE OF PURITY
>90%

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 ink jet cartridges. Each ink jet cartridge contains approximately 18 g of ink. The printing inks 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 water-soluble ink for use in ink-jet printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

IDENTITY OF MANUFACTURER/RECIPIENTS
EPSON Australia Pty Ltd (ABN 91 002 625 783)
3 Talavera Rd
North Ryde NSW 2113

TRANSPORTATION AND PACKAGING
The notified chemical will be imported from Japan in sealed ink cartridges. The cartridges will be packed in sturdy cardboard boxes and 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 containing the notified chemical will be delivered to the 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

Exposure to the notified chemical during the importation transport and storage of the printer cartridges is not expected except in the unlikely event of an accident where the sealed cartridge and its packaging may be breached. The cartridges will be distributed to a number of outlets, the cardboard cartons opened and individual boxes stacked on shelves.

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
Printer ink is imported in ready-to-use cartridges (containing < 5% notified chemical). No release is expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE
Release of the ink solution to the environment is not expected under normal use as ink cartridges are designed to prevent leakage. Spent cartridges will be replaced by service technicians, office workers

or by the public. However, if leakage or spill does occur, the ink will be contained with absorbent material, which is likely to be disposed of in landfill.

Ultimately, practically all the notified chemical will be released to the environment. Paper which the notified chemical will be bound to will eventually be buried in landfill or incinerated, or the chemical may be released in effluent from de-inking processes. Residues left in empty cartridges 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.

5.5. Disposal

The total import volume of the notified polymer will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper containing the printer ink may be disposed of directly to landfill with the notified chemical strongly bound to the paper. In addition to landfill, some of the printed paper will enter the paper recycling process.

5.6. Public exposure

The ink containing the notified chemical is dissolved in a liquid medium, so discrete particles are not released when the cartridge is in use, preventing the possibility of exposure to airborne particles. The small distance between the cartridge head and the paper minimises the exposure due to airborne dispersal of the ink droplets. 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.

Members of the public may be exposed to the notified chemical through handling of the printed paper. Assuming 1 g of ink produces 3000 A4 pages of text, each page contains 0.015 mg of dye. Once printed onto paper the notified chemical is bound and unavailable for release. Nevertheless, exposure is possible from handling printed pages prior to the ink being fully dried or if a non-absorbent substrate is placed in the printer. Exposure is also possible from residues in the printer although the cartridges are designed to minimise these residues.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Dark blue crystalline solid

Melting Point/Freezing Point Decomposes at 335°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The chemical decomposes prior to melting.
TEST FACILITY SafePharm Laboratories (2003a)

Density 1610 kg/m^3 at 21°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY SafePharm Laboratories (2003b)

Vapour Pressure <4.1 x 10^{-5} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure at 25°C was determined using a vapour pressure balance and linear regression analysis. This imposes a slope of –1500 K (an in-house value for the shallowest slope) on a chosen data point such as the reading at 200°C for the test sample of the notified chemical considered being under vacuum for the longest period prior to the test and so degassing would have been the most complete.
TEST FACILITY SafePharm Laboratories (2003c)

Water Solubility 270-280 g/L at 20°C

METHOD OECD TG 105 Water Solubility.

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

Remarks: Flask method was used, however, no analysis could be performed due to the high solubility of the notified chemical producing unfilterable mixtures and thus the water solubility was estimated based on visual inspection.

TEST FACILITY: SafePharm Laboratories (2003a)

Hydrolysis as a Function of pH Not determined.

Remarks: While one potentially hydrolysable group is present, the test material contains complex components; as such the monitoring of these components would be extremely difficult.

Partition Coefficient (n-octanol/water) log Pow = -3.91at 20ºC

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

Remarks: Test was performed using the shake-flask method at pH 7.

TEST FACILITY: SafePharm Laboratories (2003a)

Adsorption/Desorption log K_{oc} = <1.25

METHOD: HPLC screening method. Method C19 of Commission Directive 2001/59 EC (which constitutes Annex V of Council Directive 67/548/EEC).

Remarks: Test was performed using the HPLC screening method at pH 7. The notified chemical eluted before the standard solution of acetanilide, indicating it is highly mobile in soil or sediment.

TEST FACILITY: SafePharm Laboratories (2003b)

Dissociation Constant Not determined

Remarks: The notified chemical is a salt of a strong acid, which is expected to remain dissociated under all environmental pH conditions.

Particle Size The proportion of chemical with particles <100µm is 6.9%.

METHOD: Acquired using a procedure designed to comply with European Commission technical guidance document 'Particle Size Distribution, Fibre Length and Diameter Distribution' (June 1996), which satisfies the requirements of OECD Guideline 110.

Remarks: The test results indicate that the test material can be considered as essentially non-inhalable.

TEST FACILITY: SafePharm Laboratories (2003b)

Surface Tension 71.9 mN/m at 20ºC

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

Remarks: By the ISO 304 ring method, the surface tension of a 1.03 g/L solution of the notified chemical was determined with the result not being corrected using the Harkins-Jordan correction table as the correction was not considered applicable to the apparatus used (interfacial tension balance). The notified chemical is not a surface active substance.

TEST FACILITY: SafePharm Laboratories (2003b)

Flash Point Not applicable

METHOD: EC Directive 92/69/EEC A.9 Flash Point.

Remarks: Solid at room temperature

Flammability Limits Not highly flammable.

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

Remarks Test material failed to ignite in the preliminary screening test.
TEST FACILITY SafePharm Laboratories (2003d)

Autoignition Temperature 331°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY SafePharm Laboratories (2003c)

Explosive Properties Not determined

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks There are no chemical groups that would imply explosive properties.
TEST FACILITY SafePharm Laboratories (2003c)

Reactivity Not determined

Remarks The chemical is considered to be stable. Hence there are no known hazardous decomposition products. However, the chemical is combustible and will burn if involved in a fire, evolving noxious fumes such as CO_2, CO, SO_2, NO_x.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation	As the fraction of particles in the inhalable range (≤10 μm) is < 7%, the acute inhalation toxicity was not investigated.
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	Severely irritating
Guinea pig, skin sensitisation – Local Lymph Node Assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 1000 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley CD
Vehicle Distilled water
Remarks - Method Two groups of 3 female rats were dosed with 2000 mg/kg/day bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 female	2000	0/3
II	3 female	2000	0/3

LD50 > 2000 mg/kg bw
Signs of Toxicity Blue-coloured diarrhoea and stain on bedding were observed in Group I females 2 to 4 hours after dosing. Blue-stained faeces was observed in all treated animals 1 to 3 days after dosing.
Effects in Organs Group II females had dark kidneys at necropsy. No abnormalities were seen on Group I females at necropsy.

Remarks - Results	No mortality was observed in both study groups. All animals appeared normal three or four days after dosing, and showed body weight gains over the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2003e)

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Distilled water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight erythema was noted on all treated skin sites one and two days after treatment. Two treated skin sites had erythema for three days and one had erythema, which persisted for up to five days after treatment.
Signs of Toxicity - Systemic	None
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	No mortality was observed during the study. Blue-coloured staining was noted on all treated skin sites but the staining did not preclude the evaluation of erythema.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	SafePharm Laboratories (2003f)

7.3. Acute toxicity - inhalation

An acute inhalation toxicity study was not conducted for the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	No evidence of skin irritation was noted during the study. All Draize scores were zero.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	SafePharm Laboratories (2003g)

7.5. Irritation - eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Observation Period	21 days
Remarks - Method	Initially a single animal was tested to evaluate possible ocular effects. After consideration of the ocular responses, two additional animals were tested.

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	0.67	0.67	2	2 days	0
Conjunctiva: chemosis	0	0.33	0.33	1	1 day	0
Conjunctiva: discharge	0	0.33	0.33	2	1 day	0
Corneal opacity	0	0	0	0	0 days	0
Iridial inflammation	0	0	0	0	0 days	0

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

Remarks - Results	No inflammation of the cornea or iris was observed. Two treated eyes had moderate redness of the conjunctiva at 1 hour, which was slight by 24 and 48 hours. Slight chemosis and moderate discharge was observed, which resolved by 48 hours. Blue coloured residual material was noted around the treated eyes of 2 animals, which persisted up to 48 hours in one animal. Blue coloured staining of the conjunctival membranes and fur around the treated eyes were noted in all treated animals throughout the study.
CONCLUSION	The notified chemical is severely irritating to the eyes on the basis of conjunctival staining persisting to the end of the observation period.
TEST FACILITY	SafePharm Laboratories (2003h)

7.12T. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/(CBA/CaBk)
Number of Animals	16 female
Vehicle	Dimethyl sulphoxide
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration (% w/w) in dimethyl sulphoxide	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
5	1166.97	1.77
10	1153.09	1.75
25	943.13	1.43
Vehicle control: Dimethyl sulphoxide	659.94	Not applicable
Concentration (% v/v) in acetone/olive oil 4:1	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Positive control: α-hexylcinnamaldehyde		
5	-	2.8
10	-	2.3
25	-	5.5

- proliferative response not provided

Remarks - Results	No deaths occurred. Blue staining of the fur was noted in all test animals during the study. No signs of systemic toxicity were noted during the study.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Safepharm Laboratories (2003i)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Post-exposure observation period: 14 days (high dose and control groups)
Vehicle	Water
Remarks - Method	Additional 14-day recovery groups were also included for high dose and control groups.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	100	0
III (mid dose)	5/sex	300	0
IV (high dose)	5/sex	1000	0
V (control recovery)	5/sex	0	0
VI (high dose recovery)	5/sex	1000	0

Mortality and Time to Death

No mortalities were observed.

Clinical Observations

There were no clinical effects observed during the study. No abnormalities were seen in the detailed observations of general condition, food intake and functional examinations. Blue colouration was seen in urine

and faeces of all treated animals. Females of the high dose group showed increased body weight gain compared with the control group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Decreased blood urea nitrogen (BUN) level and total protein in high dose males compared with control group. Decreased albumin/globulin ratio was observed in the high dose recovery group.

Haematology

Prolonged activated partial prothrombin time (APTT) in high dose females compared with control group was observed. In the high dose recovery group, decreased platelet count was observed.

Urinalysis

No abnormalities apart from the blue colouration of urine were seen.

Effects in Organs

No changes were seen in the organ weights. At necropsy, intestinal contents below the ileum showed blue discolouration.

Microscopic findings

Small granulation foci in the liver and eosinophilic bodies in the proximal tubular epithelium of the kidneys were seen in high dose and control groups. At necropsy, the renal cortex showed blue colouration.

Remarks – Results

The slight decreased in the clinical chemistry and haematology parameters in the high dose groups were not considered test substance related because the differences compared with the control were minimal and considered within the physiological variation.

In the recovery group, the blue colouration of urine and faeces disappeared on day 1 and day 7 of the recovery period, respectively, and the colour of the alimentary tract contents was normal at necropsy. Blue colouration of the renal cortex was not considered to be related to the toxic effects of the test material since there were no changes detected in the histopathological examinations at necropsy. In addition, the presence of sporadic small granulation foci in the liver and eosinophilic bodies in the proximal tubular epithelium of the kidney are common spontaneous lesions in the strain of animals used and therefore not considered to be related to the test material.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg /day bw in this study, the highest dose tested.

TEST FACILITY Saitama Laboratory (2002)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE

METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test and EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli* WP2 *uvr*A
Metabolic Activation System	Rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate. b) Without metabolic activation: 0 - 5000 µg/plate.
Vehicle	
Remarks - Method	Two independent tests were performed in duplicate.

RESULTS

Remarks - Results	No significant increases in the number of revertant colonies were observed in any strain at any dose level. 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	Material Safety Test Center (2002a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese Hamster Lung Fibroblasts (CHL/IU)
Metabolic Activation System	Rat liver S9 fraction following phenobarbital and 5,6-benzoflavone administration.
Vehicle	Distilled water
Remarks - Method	Test concentrations were based on a preliminary cell growth inhibition test, which was conducted at a dose range of 0.0098 to 5.0 mg/mL. Based on result, the approximate 50% cell growth inhibition dose was found to be 5 mg/mL (the highest dose tested) for both the short and continuous treatment regimes.

Metabolic Activation	*Test Substance Concentration (mg/mL)**	*Exposure Period*	*Harvest Time*
Absent			
Test 1			
Short term	1.3, 2.5 and 5.0	6 hours	24 hours
Continuous	1.3, 2.5 and 5.0	24 and 48 hours	24 and 48 hours
Test 2			
Short term	1.3, 2.5 and 5.0	6 hours	24 hours
Continuous	1.3, 2.5 and 5.0	24 and 48 hours	24 and 48 hours
Present			
Test 1			
Short term	1.3, 2.5 and 5.0	6 hours	24 hours
Test 2			
Short term	1.3, 2.5 and 5.0	6 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results	No significant increase in the percentage of cells with chromosomal aberrations was observed in the cell growth inhibition test (Test 1). Also, no precipitation of the notified chemical was seen. The notified chemical did not increase the percentage of cells with chromosomal aberrations. No precipitation of the notified chemical was observed.

Appropriate positive controls gave the expected responses.

CONCLUSION — The notified chemical was not clastogenic to Chinese Hmanster Lung fibroblasts treated in vitro under the conditions of the test.

TEST FACILITY — Material Safety Test Center (2002b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability (test 1)

TEST SUBSTANCE — Notified chemical

METHOD
- Inoculum: Standard activated sludge
- Exposure Period: 28 days
- Remarks - Method: The method followed that described in the OECD Guidelines for Testing Chemicals (1992) No. 301B, "Ready Biodegradability; CO_2 Evolution Test" referred as Method C.4-C of Commission Directive 92/69/

The test material and reference material (sodium benzoate), at the concentration of 10 mg C/L, were exposed to activate sewage sludge micro-organisms with culture medium in sealed culture vessels in the dark at 21°C for 28 days.

The degradation of the test material was assessed by the determination of carbon dioxide produced. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes.

RESULTS

Day	*Sodium benzoate % degradation*	*Test substance % degradation*	*Test substance + Sodium benzoate % degradation*
0	0	0	0
1	20	1	12
3	46	10	27
6	52	10	41
14	86	16	56
22	90	17	57
28	103	24	71
29*	108	33	75

* Day 29 values corrected to include any carry over of CO_2 detected in absorber

Remarks - Results: The total CO_2 evolution in the control on day 28 was 19.68 mg/L and therefore satisfied the validation criterion. The test material attained 24% degradation after 28 days.

CONCLUSION — The notified chemical cannot be considered to be readily biodegradable under thew strict terms and conditions of OECD Guideline No. 301B.

TEST FACILITY — SafePharm Laboratories (2003j)

8.1.1. Ready biodegradability (test 2)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Standard activated sludge
Exposure Period	14 days
Remarks - Method	Study was performed in compliance with "Biodegradability test of a chemical substance by microorganisms" as prescribed in No. 5 of "Kanhogyo", No. 615 of "Yakuhatsu" and No. 392 of "49 Kikyoku" dated July 13, 1974 and also with "Ready Biodegradability: Modified MITI Test (I)" as prescribed in "OECD Guidelines for Testing of Chemicals 301C". The biodegradation of the notified chemical was determined after the medium was inoculated with activated sludge and stored in the dark at 20ºC for 14 days. The concentrations of the test material and reference (aniline) were 100 mg/L, respectively. Test temperature: 25±1°C. Biodegradation was measured 3 ways: BOD, DOC and HPLC analysis of test substance.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
7	0	7	69
14	0	14	70

Remarks - Results	Almost no biodegradation was observed for the test material. This was confirmed by HPLC which indicated >99% of test substance remained after 14 days.
CONCLUSION	The notified chemical is not considered to be readily biodegradable under the conditions of this study.
TEST FACILITY	Material Safety Test Center (2003)

8.1.2. Bioaccumulation

A bioaccumulation study was not conducted. As Log Pow is very low (-3.91) there is no potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – semi static EC Directive 92/69/EEC C.1 Acute Toxicity for Fish
Species	Rainbow trout (*Oncorhynchus mykiss*) [juvenile]
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Chemical analysis at 0, 24, 48, 72 and 96 hours.
Remarks – Method	A range-finding test was conducted at 1.0, 10 and 100 mg ai/L. Based on the results for the range-finding test a Limit test using 3 fish per concentration was conducted at a concentration of 100 mg/L to confirm that at the maximum concentration given in the OECD/EEC Test Guidelines no mortality or sub-lethal effects of exposure were observed. 20 L glass exposure vessels were used and the photoperiod was 16 h

light: 8 h dark with transition periods. Fish were acclimated 7 days prior to testing, and no mortality was recorded prior to the tests. Analytical testing showed that the test material was stable during the tests (85-113% of nominal) and thus nominal concentrations were used. Temperature: 12.0-13.8 °C. pH 7.5-8.3. Dissolved oxygen 7.5-8.6 mg/L. Concentration of standards and test solutions were determined spectrophotometrically using an external standard.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*Mortality* *3h*	*6h*	*24h*	*48h*	*72h*	*96h*
Control	10	0	0	0	0	0	0
100 R1	10	0	0	0	0	0	0
100 R2	10	0	0	0	0	0	0

R1 and R2 = Replicates 1 and 2

LC50	>100 mg/L at 96 hours
NOEC (or LOEC)	100 mg/L at 96 hours.
Remarks – Results	The results of the definitive study showed that no mortalities were observed in the test vessels with 100 mg/L of test substance in both replicates for the duration of the tests. The very dark blue solutions were clear throughout and there were no sub-lethal effects of exposure observed in the 20 fish exposed to a test concentration of 100 mg/L for as period of 96 hours. It was considered unnecessary and unrealistic to test at concentrations in excess of 100 mg/L.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to rainbow trout.
TEST FACILITY	SafePharm Laboratories (2003k)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation/Reproduction Test-static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Analytical monitoring at 0 and 48 hours showed that the test substance was stable during the tests.
Remarks - Method	Range-finding and definitive tests were performed. At concentrations of 0.010, 0.10, 1.0 and 100 mg ai/L, no immobilisation was observed. Test concentrations (definitive test) of 1.8, 3.2, 5.6, 10, 18, 32, 56, 100 and 180 mg ai/L were employed. Photoperiod: 16 h light: 8 h dark with transition periods. Standards and test solutions were tested by HPLC. Test pH 7.9-8.0. Temperature 20.7-20.9°C. Dissolved oxygen 8.2-8.4 mg/L.

RESULTS

Concentration mg/L (Nominal)	Cumulative Immobilised *Daphnia* (Initial population: 10 per replicate)							
	24 h				*48 h*			
	R1	*R2*	*Total*	*%*	*R1*	*R2*	*Total*	*%*
Control	0	0	0	0	0	0	0	0

1.8	0	0	0	0	0	0	0	0
3.2	0	0	0	0	0	0	0	0
5.6	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
18	0	0	0	0	0	1	1	5
32	0	0	0	0	1	0	1	5
56	1	2	3	15	2	2	4	20
100	2	1	3	15	3	2	5	25
180	2	2	4	20	3	4	7	35

LC50	>180 mg ai/L at 48 hours
NOEC (or LOEC)	10 mg ai/L at 48 hours
Remarks - Results	In the definitive study, no effects were observed in the test vessels with less than 32 and 10 mg/L of test substance for periods of 24 and 48 hours respectively. These were blue solutions of increasing intensity with increasing concentration. After 48 h, 35 % immobilisation was observed at a test concentration of 180 mg/L, so an EC50 could not be calculated. It was considered unnecessary to test at concentrations above 180 mg/L in another test as the recommended test concentration in the Test Guideline is 100 mg/L at which 25% immobilisation was observed in the definitive test.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic *to Daphnia magna*.
TEST FACILITY	SafePharm Laboratories (2003l)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green algae *Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	
Nominal	1.0, 3.2, 10, 32, 100 mg/L
Auxiliary Solvent	None
Analytical Monitoring	Standards and test solutions were tested by UV-visible spectroscopy. These were 90-108% of nominal at test initiation and declined slightly by 72 h. Samples of the algal populations were measured for each control, group and treatment group, using a Coulter® Multisizer II Particle Counter.
Remarks - Method	Duplicate experiments (A and B) were performed to differentiate growth effects between toxicity and reduced light causes. Experiment A: Algae were exposed to test material in a flask enclosed from above by a petri dish containing culture medium only. Inhibition was due to a combination of toxicity and reduction in light intensity. In Experiment B, algae were not exposed to the test material in the flasks, but the flasks were enclosed by petri dishes containing the culture media and the test material. Therefore, inhibition of algal growth was due to a reduction in light intensity alone. The difference between Experiments A and B inhibition values is presumed to be due to the toxic effect of the test material on algal cells. Mean cell density in Expt. A was $1.03X10^4$ cells/mL (initial) and $2.41X10^5$ cells/mL (72 hours). Mean cell density in Expt. B was $1.08X10^4$ cells/mL (initial) and $2.33X10^5$ cells/mL (72 hours). Constant illumination and stirring. Temperature 24±1 °C. pH 7.4-7.6.
RESULTS	

Experiment	EbC50 (72 hour)	NOEC (72 hour)	ErC50 (72 hour)
A	9.4 mg ai/L	1.0 mg ai/L	39 mg ai/L
B	14 mg ai/L	1.0 mg ai/L	46 mg ai/L

Remarks - Results: Given that significant differences (greater than 10%) in the inhibition values between Experiments A and B were observed, it was considered that the effect of the test material on algal growth was not only due to a reduction in light intensity, but also due to the intrinsic toxic properties of the test material. Therefore, for classification purposes the results determined from Experiment A should be used.

CONCLUSION: The results indicated the combined toxic nature of the test material and the reduction in light intensity. The test material is toxic to algae.

TEST FACILITY: SafePharm Laboratories (2003m)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 87/302/EEC Activated Sludge Respiration Inhibition Test

Inoculum: Activated sewage
Exposure Period: 3 hours
Concentration Range Nominal: 10-3200 mg/L
Remarks – Method: Following a preliminary range-finding test using test concentrations of 1.0, 10, 100 and 1000 mg/L, activated sludge was exposed in the definitive test to an aqueous solution of the test material at the test concentration of 1000 mg/L in a "limit test" of for a period of 3 hours at 21°C with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.

RESULTS

	EC50 (30 min) [mg/L]	EC50 (3 hours) [mg/L]
Test substance	>1000	>1000
Reference	20	14
Variation in respiration rate of controls 1 and 2.	±2%	±10%

EC50: >1000 mg/L
NOEC: 1000 mg/L
Remarks – Results: The validation criteria for the control respiration rates and reference material EC50 values have been satisfied. It was considered unnecessary and unrealistic to test at concentrations in excess of 1000 mg/L.

CONCLUSION: The effect of the test material on the respiration of activated sludge micro-organisms gave a 3-hour EC50 of greater than 1000 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 1000 mg/L.

TEST FACILITY: SafePharm Laboratories (2003n)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The environmental safety controls and use pattern for the notified chemical would indicate a limited potential for its release into the environment.

The notified chemical is soluble in water; however, aquatic release is considered unlikely and after drying the notified chemical is likely to be stable within an inert matrix on printed paper products.

Emptied ink cartridges containing a residue of notified chemical will be sent to landfill for disposal. While in a landfill the notified chemical is expected to be mobile, it will be widely dispersed and eventually it will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

A proportion of the paper products containing the notified chemical may form litter; however, the expected small quantity and stable form is unlikely to pose an unacceptable risk to the environment.

Incineration of waste paper and sludges will destroy the compound with the generation of water vapour and oxides of carbon and nitrogen. Due to its solubility, wastewaters from paper recycling facilities are expected to contain the notified chemical, with some adsorbed to solids and settled as sludges within on-site wastewater treatment plants (WWTPs). Raw wastewaters are typically treated prior to discharge to sewer. While it is not possible to quantify a WWTP effluent discharge concentration, if is assumed that 50% of printed paper is recycled, 50% of this is in the supernatant effluent discharged to sewer (assuming no WWTP attenuation and a discharge of 1% of the Australian total wastewater flow of 1.46×10^{12} L/annum), the predicted environmental concentration (PEC) of the notified chemical would be <0.017 mg/L.

It is, however, expected that there will be minimal release to water. In addition, bioaccumulation is not expected due to the low log Pow of the notified chemical, implying low lipid solubility, and its large molecular weight range (around 1319 - 1433 g/mol), which inhibits passage through cell membranes.

Although the notified chemical is not considered to be readily biodegradable, biodegradation is expected to occur overtime. The low octanol-water partition coefficient and high water solubility indicate the notified chemical will be predominantly distributed in water, where it will become diluted and dispersed and eventually partition to sediment.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified chemical is acutely toxic to algae but not to fish and *Daphnia magna*. The most sensitive species are algae, where the 72 hour EbC50 is 9.4 mg/L. Acute results are available for 3 trophic levels, so an assessment factor of 100 may be applied to the most sensitive species (algae), giving a predicted no effect concentration (PNEC) of 94 μg/L.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (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 cartridges, release of the notified chemical to the environment is expected to be low and widespread.

The PEC/PNEC ratio for the aquatic environment, assuming a worst case, is 0.18. This value is less than 1, indicating a low risk to the aquatic compartment. The notified chemical will interact with other components to form a stable chemical matrix and, once dry, is expected to be immobile and pose little risk to the environment. The notified chemical is not likely to present a hazard to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

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, except on rare occasions where the ink has not completely dried or is printed to non-absorbent substrate.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached, and even in this case only small amounts of the notified chemical will be involved.

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 substrate treated with ink containing <5 % notified chemical, as discussed above.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral and dermal toxicity in rats (LD50 >2000 mg/kg bw), was not a skin irritant but a severe eye irritant based on the persistent discolouration on the conjunctival membranes. The notified chemical did not show evidence of skin sensitisation potential in guinea pigs, was not mutagenic in bacteria and did not induce chromosomal aberrations in mammalian cells in vitro. The NOAEL in a 28-day oral repeat dose study in rats was 1000 mg/kg/day bw, the highest dose tested.

9.2.4. Occupational health and safety – risk characterisation

Exposure to the ink containing the notified chemical during transport of pre-packed cartridges should not occur except in the event of accidental spillage.

The notified chemical is a severe eye irritant. However, the overall risk of adverse effects arising from exposure to the notified chemical is low due to its low concentration in the ink and the low potential for exposure. Printers should be located in well-ventilated areas.

Overall, the occupation risk posed by the notified chemical is low when used as specified in the notification because of the low concentration of the notified chemical in the ink (<5%), the limited contact to the ink when in use, and the use of protective equipment during printer maintenance.

9.2.5. Public health – risk characterisation

There is low potential for public exposure to the notified chemical during transportation, unless accidental spillage occurs. In addition, members of the public are not likely to make contact with the notified chemical during cartridge changes unless the cartridge is ruptured or otherwise

tampered with. The public could potentially contact the ink before it is completely dry on the paper substrate but deliberate and inadvertent smudging of printed documents is not a common practice. Once the ink containing the notified chemical is deposited on the printed pages, it will be bound to the paper and is not bioavialable.

In view of its physical and chemical properties, its low proportion in the ink, and the pattern of package and usage of the ink cartridge, the notified chemical is unlikely to pose a significant hazard to public health.

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* (NOHSC, 1999). The classification and labelling details are:
R41: Risk of serious damage to eyes

and

As a comparison only, the classification of 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.

Eye Irritant Category 1:
Symbol: Corrosive
Signal Word: Danger
Hazard Statement: Causes severe eye damage

Chronic Hazards to the Aquatic Environment Category 2:
Symbol: Environment
Signal Word: No signal word
Hazard Statement: Toxic to aquatic life with long lasting effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified 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 pre-packed ink cartridges.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It 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, 1994). 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:
  - R41 Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\geq$ 10%: R41
  - 5% $\leq$ concentration $\leq$ 10%: R36

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 guideless 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

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified chemical should be disposed of by incineration or to landfill in accordance with State/Territory waste disposal regulations. Paper products impregnated with ink containing the notified chemical may be incinerated, recycled or landfilled.

Emergency procedures

- Spills/release of the notified chemical should be handled by mechanically collecting spilled material (eg. sweeping dried material). Avoid raising dust. Do not allow material to contaminate ground, groundwater or waterways. Prevent product from entering

drains or stormwater system.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical; or

or

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

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

Material Safety Test Centre (2002a) Reverse Mutation Study Of 01557 In Bacterial Strains. Study no. M-02005. Material Safety Test Centre, Environmental Protection and Products Safety Division, Fuji Photo Film Co., Ltd, Japan. Ashigara Research Laboratory; Fuji Photo Film Co., Ltd (unpublished report submitted by Epson Australia, Pty Ltd).

Material Safety Test Centre (2002b) Chromosome Aberration Study of 01557 In Cultured Mammalian Cells. Study no. A-02005. Material Safety Test Centre, Environmental Protection and Products Safety Division, Fuji Photo Film Co., Ltd, Japan. Ashigara Research Laboratory; Fuji Photo Film Co., Ltd (unpublished report submitted by Epson Australia, Pty Ltd).

Material Safety Test Centre (2003) Biodegradability study of 01557. Study no. B-02014. Material Safety Test Centre, Environmental Protection and Products Safety Division, Fuji Photo Film Co., Ltd, Japan. Ashigara Research Laboratory; Fuji Photo Film Co., Ltd (unpublished report submitted by Epson Australia, Pty Ltd).

NOHSC (2003). National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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

SafePharm Laboratories (2003a) FYS-108: Determination of General Physico-Chemical Properties Project no. 1307/149. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003b) FYS-108: Determination of General Physico-Chemical Properties (Annex VIIA). Project no. 1307/171. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003c) FYS-108: Determination of Hazardous Physico-Chemical properties. Project no. 1307/172. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003d) FYS-109: Determination of Flammability (Solids). Project no. 1307/150. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003e) FYS-108: Acute Oral Toxicity In The Rat – Acute Toxic Class Method. Project no. 1307/151. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003f) FYS-108: Acute Dermal Toxicity (Limit Test) In The Rat. Project no. 1307/152. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003g) FYS-108: Acute Dermal Irritation In The Rat. Project no. 1307/153. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003h) FYS-108: Acute Eye Irritation In The Rabbit. Project no. 1307/154. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003i) FYS-108: Local Lymph Node Assay In The Mouse. Project no. 1307/309. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003j) FYS-108: Assessment of ready biodegradability; CO2 Evolution Test. Project no. 1307/244. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003k) FYS-108: Acute Toxicity to Rainbow Trout. Project no. 1307/156. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003l) FYS-108: Acute Toxicty to Daphnia Magna. Project no. 1307/157. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003m) FYS-108: Inhibition of Algal Growth Caused by Coloured Test Substances. Project no. 1307/158. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

SafePharm Laboratories (2003n) FYS-108: Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge. Project no. 1307/159. Derbyshire, UK, SafePharm Laboratories Limited (unpublished report submitted by Epson Australia, Pty Ltd).

Saitama Laboratory (2002) FYS-108: Twenty-Eight Day Repeated Dose Oral Toxicity Study. Study no. 0227-2. Saitama Laboratory, Drug Safety Testing Centre Co., Ltd., Japan (unpublished report submitted by Epson Australia, Pty Ltd).

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.