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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

FYS-109

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Epson Australia Pty Ltd (ABN 91 002 625 783) of 3 Talavera Road North Ryde NSW 2113.

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

The notified chemical is assessed under the standard category as advised by the notifier although its introduction volume will be 1 tonne or less per year.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Additives/Adjuvants, Use Details, and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: Dissociation Constant, Flash Point.
Part C: Acute Inhalation Toxicity, In Vivo Genotoxicity, Daphnia Reproductive Toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Low volume chemical permit (2003)

NOTIFICATION IN OTHER COUNTRIES
UK: 03-06-1670 (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FYS-109 (notified chemical)
Epson Black Ink Cartridges T0483 and T0486

3. COMPOSITION

DEGREE OF PURITY
Medium to high

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import

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

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

USE
As a component (<5%) of liquid ink formulations.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Epson Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be transported by road and distributed as a component of an end-use product in sealed cartridges packed in carton boxes.

5.2. Operation description

No manufacturing, reformulation, filling or refilling of cartridges will occur in Australia. When replacing ink cartridges, the public, office staff or a trained engineer will follow replacement procedures recommended by the manufacturer. This involves removing the seal tape and inserting the cartridge into printers. Spent cartridges will be disposed of with normal office/domestic waste.

5.3. Occupational exposure

Number and Category of Workers
The notified chemical will be handled only within sealed cartridges, and on an occasional basis, by a large number of retail and office workers and a limited number of transport and storage workers, and by service engineers.

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

Office staff and service engineers may be intermittently exposed to the notified chemical contained in the cartridge via skin contact when replacing the spent cartridges, cleaning paper jams or during maintenance and servicing. The service engineers will wear gloves and receive appropriate training in servicing techniques.

Contact with paper printed with the ink containing the notified chemical is unlikely to result in dermal exposure as the chemical will be bound within the matrix of the paper and become inert, except if the paper or other substrate is handled before the ink has dried.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Printer ink will be 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. If leakage or spill does occur, 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. 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 chemical will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified chemical bound to the paper. Some will enter the paper recycling process.

5.6. Public exposure

Public exposure may potentially occur from contact with printed media containing the notified chemical, residues in the printer, and during cartridge replacement. However, the liquid ink containing the notified chemical is held on an absorbent within sealed cartridges which are not expected to leak during normal use, while the ink deposited on the printed pages is bound to the paper and hence not biologically available once dried. Further, the cartridge is enclosed within the body of the printer and the distance between the cartridge head and the paper is very small so that the chance of airborne dispersal of the ink droplets out of the printer is negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Dark red crystalline powder with no odour

Melting Point >360°C

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature – ASTM E537-86.
Remarks	By differential scanning calorimetry, the notified chemical was determined to decompose prior to melting, from approx. 360°C. Similar thermographic profiles were also obtained using air and nitrogen atmospheres, indicating the observed decomposition with low rate of enthalpy is probably thermal and not oxidative.
TEST FACILITY	SPL (2003a)

Density 1490 kg/m^3 at 20°C

METHOD	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Testing was performed using a gas comparison pycnometer.
TEST FACILITY	SPL (2003b)

Vapour Pressure <1.9x10^{-8} kPa at 25°C (estimate)

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 193°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	SPL (2003c)

Water Solubility 514 –537 g/L at 20°C

METHOD	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	SPL (2003a)

Hydrolysis as a Function of pH $t_{½}$ >1 year at 25ºC at any pH (estimate)

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks The preliminary test showed less than 10% hydrolysis after 5 days at 50ºC in buffers of pH 4, 7 and 9, which is estimated to be equivalent to a half-life of >1 year at 25ºC at any pH.
TEST FACILITY SPL (2003b)

Partition Coefficient (n-octanol/water) log Pow = -3.03 at 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 SPL (2003a)

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

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
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 SPL (2003b)

Dissociation Constant Not determined

Remarks Test was not performed as the notified chemical contains both acidic and basic functional groups with overlapping pKa. An additional complication for accurate determination of the pKa is the presence of impurities together with water solubility which could not be measured analytically.

Particle Size

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

Range (μm)	*Mass (%)*	*Method*
<100	14.7%	Sieve
<10	0.9%	Cascade Impactor

Remarks The proportion by mass of particles which, if inhaled, can be expected to achieve deposition throughout the respiratory tract is 0.9%.
TEST FACILITY SPL (2003b)

Surface Tension 69.7 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. The notified chemical is not a surface active substance.
TEST FACILITY SPL (2003b)

Flash Point Not determined

Remarks The notified chemical is a solid at room temperature.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical failed to ignite during the two minutes the Bunsen flame was applied, and thus obviating the need to perform the main test.

TEST FACILITY SPL (2003d)

Autoignition Temperature >400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Black charred remains were observed after the test.
TEST FACILITY SPL (2003c)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Tests of both mechanical sensitivity (BAM fall hammer and friction tests) and thermal sensitivity (Koenen steel tube test) were performed.
TEST FACILITY SPL (2003c)

Oxidizing Properties Not oxidising (predicted)

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Test was not performed as the notified chemical contains no chemical groups that would imply oxidising properties.
TEST FACILITY SPL (2003c)

Reactivity Stable under normal environmental conditions

Remarks There are no known hazardous decomposition products or incompatibility with other substances. However, the notified chemical is combustible and will burn in a fire, evolving noxious fumes such as oxides of carbon, sulphur, and nitrogen.

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	no data available
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	severely irritating
Skin sensitisation – local lymph node assay	evidence of sensitisation
Rat, repeated dose oral toxicity – 28 days	NOEL = 250 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic
Genotoxicity – in vivo studies	no data available
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

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 No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*

I	3 females	2000	0/3
II	3 females	2000	0/3

LD50	>2000 mg/kg bw
Signs of Toxicity	All animals showed dark red staining of the fur throughout the 14-day study period and red stained faeces and/or dark red stained urine up to three days after dosing. Weight gain was as expected.
Effects in Organs	Dark liver and kidneys (stained red) were noted at necropsy in all animals.
Remarks - Results	None.

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

TEST FACILITY SPL (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 (moistened)
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 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation were noted.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted. All animals showed expected weight gains.
Effects in Organs	No macroscopic abnormalities were noted at necropsy.
Remarks - Results	Red coloured staining was noted at the treatment sites of all animals after 1 day dosing, of all females 2-5 days after dosing, and of one female 6 days after dosing. These were considered to prevent the evaluation of erythema.

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

TEST FACILITY SPL (2003f)

7.3. Acute toxicity – inhalation

Remarks Test was not performed due to the low volatility of the notified chemical and less than 0.1% of its particles having an aerodynamic diameter <10 μm.

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 males
Vehicle	Distilled water (moistened)
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	There is no evidence of skin irritation or corrosion during the study. Primary irritation index = 0 (non irritating). Pink coloured staining was noted at two treated skin sites, however this was considered not to affect evaluation of skin reactions.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY SPL (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 males
Observation Period	14 days
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.0	2.0	2.0	2	7 d	0
Conjunctiva: chemosis	2.3	2.3	2.3	3	7 d	0
Conjunctiva: discharge	2.3	2.3	2.0	3	7 d	0
Corneal degree of opacity	1.0	1.0	1.0	1	72 h	0
Corneal: area of cornea involved	3.3	3.3	2.0	4	72 h	0
Iridial inflammation	1.0	1.0	1.0	1	72 h	0

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

Remarks – Results	Moderate to severe conjunctival irritation was noted in all treated eyes 1 h after treatment with severe irritation observed at 24 h, moderate irritation at 48 and 72 h, and slight irritation at 7 d. Scattered or diffuse corneal opacity and iridial inflammation were noted in all treated eyes at 24, 48 and 72 h observations. Treated eyes appeared normal at the 14 d observation. Pink coloured staining of the fur and the cornea and/or conjunctiva was noted in all treated eyes during the study and on occasions prevented the evaluation of conjunctival redness. Staining of conjunctival membranes persisted beyond 14 days in all animals. Pale appearance or haemorrhage of nictitating membrane was also noted.

CONCLUSION The notified chemical is severely irritating to the eyes.

TEST FACILITY SPL (2003h)

7.6. Skin sensitisation – local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (LLNA)
Species/Strain	Mouse/CBA CaBkl
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks – Method	No significant protocol deviations.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	955	--
5	1290	1.35
10	1682	1.76
25	5870	6.15
*Positive Control**		
5	not reported	2.8
10	not reported	2.3
25	not reported	5.5

* hexyl cinnamic aldehyde in 4:1 acetone/olive oil.

Remarks - Results	The notified chemical showed a stimulation index (SI) of >3 with the 25% solution, thus is considered as a sensitiser under the conditions of the test. Red coloured staining of the fur was noted in all test animals during the study. No signs of systemic toxicity or deaths were observed. Body weight changes were comparable between the test and control animals.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	SPL (2003i)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Japan MHW Repeated Dose (28 Days) Toxicity in Mammalian Species.
Species/Strain	Rat/Wistar
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0/10
II (low dose)	5 per sex	60	0/10
III (mid dose)	5 per sex	250	0/10
IV (high dose)	5 per sex	1000	0/10
V (control recovery)	5 per sex	0	0/10
VI (high dose recovery)	5 per sex	1000	0/10

Mortality and Time to Death
No mortalities were seen during the study.

Clinical Observations
No abnormalities were seen in behaviour, detailed clinical observations or functional tests in any dose groups.

Faeces coloured red (similar colour to the dosing solution) were seen throughout the administration period in the high dose group, after 2 days in the mid dose group, and after 11 days in the low dose group. Staining of perianal region was also observed. In the recovery group, the faecal coloration and perianal staining disappeared on day 2 and 4 onwards respectively after the end of administration.

Changes observed in the high dose group only include reduced body weight gain from the beginning of administration period (statistical significance on day 7 after administration in males), and lowered food consumption after one day of administration. During the recovery period, body weight gain and food consumption were same between the high dose and control group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
High dose males showed lowered values of erythrocyte count, haemoglobin concentration, haematocrit, and mean corpuscular volume, which were correlative and significant changes suggesting anaemia. However, there was no haemorrhage from the digestive tract or changes in the bone marrow in histopathological examination. Therefore, the cause of these observations in the males was unclear. Elevation of leukocyte count was also seen in the high dose males, and this change might be related to the small round cell infiltration into the portal region in the liver. However, no changes were seen in any parameters in females. In the recovery group, changes observed at the end of the administration period had resolved apart from mean corpuscular volume in males. Changes such as lowered values of mean corpuscular haemoglobin, elevation of reticulocyte count, and prolongation of activated partial thromboplastin time were minor and considered to be within physiological variation.

Total protein, albumin, globulin, and triglyceride showed lowered values in the high dose group, possibly relating to the reduced body weight gain, and these changes appeared to be treatment related. However, elevation of GOT (glutamic oxaloacetic transaminase) in female and lowered levels of alkaline phosphates and BUN (blood urea nitrogen) in male were either only slightly out of or within the normal background data and occurred only in one sex, therefore these changes were considered unrelated to treatment. In the recovery group, lowered values of total protein, globulin and triglyceride were seen in males, and were considered to be the continuation of the lowered level seen at the end of the administration period.

Urine was not stained, and no changes in urinalysis parameters were observed.

Effects in Organs
In pathological examination, relative weights of the kidney, heart, and testes in the high dose group were increased and adrenals and uteri showed increase in absolute and relative weights. These changes were considered to be non-specific, probably relating to the reduced body weight gain. In the recovery group, similar changes to those observed at the end of administration period in the kidney, heart and testes were seen. Relative weights of the liver, spleen, pituitary, and epididymides were increased, however, these were minor and also considered to be non-specific. There was a minor decrease in absolute thymus weight in females, but this was not considered to be treatment related.

In histopathological examination, small round cell infiltration into portal region (slight to moderate degree) in the liver, and vacuolar degeneration of tubular epithelium (slight) in the kidney were seen in all high dose males and females. These changes were considered treatment related as none of them were seen in the control group. In the recovery group, the infiltration into portal region in the liver was not seen, while the degeneration of tubular epithelium in the kidney became minor both in males and females, suggesting that these effects are reversible.

No clear histopathological changes corresponding to the macroscopic findings of red coloration of the renal cortex were observed. Small granulation foci in the liver observed in the high dose animal were seen in a similar degree to the control group, and no differences were seen in incidence or severity between these two groups, and thus the effect was not considered treatment related.

Remarks – Results

In the mid dose group, there were no changes considered to be treatment-related. Changes observed in histopathological examination (such as eosinophilic bodies in the kidney proximal tubular epithelium and small granulation foci in the liver) were scattered and considered common spontaneous lesions in the rats of same strain used in the study.

In the low dose group, lowered value of ovary weight was minor variation within the background data, and the change seen in histopathological examination was small granulation foci. These were not considered treatment related.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 250 mg/kg bw/day in both male and female in this study, based on haematology and clinical chemistry.

TEST FACILITY Saitama Laboratory (2002)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9 fraction from phenobarbital and β-naphthoflavone induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 313, 625, 1250, 2500, 5000 µg/plate. b) Without metabolic activation: 313, 625, 1250, 2500, 5000 µg/plate.
Vehicle	Sterilised distilled water
Remarks – Method	The retest was only performed on TA1537 with metabolic activation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Geno toxic Effect*
Absent				
Test 1	>5000	>5000	>5000	Negative
Present				
Test 1	>5000	>5000	>5000	Negative
Test 2 (TA1537 only)	--	>5000	>5000	Negative

Remarks - Results The notified chemical did not induce a 2-fold or more increase in the number of revertant colonies compared to the negative control, either with or without metabolic activation. The revertant colony counts on the positive control plates of TA1537 with metabolic activation were 243 (mean), which were out of the control range of 260-697 of the testing facility, and thus they were not included in the analysis, but those obtained in the retest were used.

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

TEST FACILITY ME (2002a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. Japan MHW Chromosomal Aberration Test
Cell Type/Cell Line: Chinese hamster pulmonary fibroblast (CHL/IU)
Metabolic Activation System: S9 fraction from phenobarbital and β-naphthoflavone induced rat liver.
Vehicle: Sterilised physiological saline
Remarks - Method: The treatment regime for 1.5 and 3.0 cell cycle lengths was adopted to Ishidate's method (Ishidate, 1987).

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1 (short term)	0.0098, 0.020, 0.039, 0.078, 0.16*, 0.31*, 0.63*, 1.3*, 2.5*, 5.0	6 h	24 h
Test 2 (1.5 cell cycle)	0.0098, 0.020, 0.039, 0.078*, 0.16*, 0.31*, 0.63*, 1.3*, 2.5, 5.0	24 h	24 h
Test 3 (3.0 cell cycle)	0.0098, 0.020, 0.039*, 0.078*, 0.16*, 0.31*, 0.63, 1.3, 2.5, 5.0	48 h	48 h
Present			
Test 1 (short term)	0.0098, 0.020, 0.039, 0.078, 0.16, 0.31, 0.63, 1.3, 2.5, 5.0 0.28*, 0.55*, 1.1*, 2.2*	6 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	Not performed	≥1.3	>5.0	Negative
Test 2	Not performed	≥0.63	>5.0	Negative
Test 3	Not performed	≥0.16	>5.0	Negative
Present				
Test 1	Not performed	≥1.1	>5.0	Negative

Remarks - Results: The frequency of cells with structural aberrations was less than 5% at any dose level as a result of microscopic examination in the short term and continuous treatment regimes, therefore, the notified chemical is considered not to be clastogenic. The result of the vehicle and positive controls confirm the sensitivity of the test system.

CONCLUSION: The notified chemical was not clastogenic to CHL/IU cells treated in vitro under the conditions of the test.

TEST FACILITY: ME (2002b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 C Ready Biodegradability: Modified MITI Test (I). 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
Inoculum: Standard activated sludge
Exposure Period: 28 days

Remarks - Method: The concentrations of the test material and reference (aniline) for testing were 100 mg/L. Test temperature: 25±1°C. Biodegradation was calculated from BOD (biochemical oxygen demand), TOC (total organic carbon) and HPLC analysis of test substance.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
7	0	7	63
14	0	14	70
28	0	28	72

Remarks - Results: No biodegradation was observed for the notified chemical. The percentage degradation calculated from BOD and TOC analysis was 0% and 1% on average respectively. The residual rates calculated from HPLC analysis were 99%-100% on average.

CONCLUSION: The notified chemical is not considered to be readily biodegradable under the conditions of this study.

TEST FACILITY: ME (2003)

8.1.2. Bioaccumulation

A bioaccumulation study was not conducted. As Log Pow is very low (-3.03) 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 and 96 hours.
Remarks – Method: Range-finding and definitive tests were conducted. The range finding test was conducted at 1.0, 10 and 100 mg ai/L. Based on the results for the range-finding test, the following test concentrations were used for the definitive test (1.0, 1.8, 3.2, 5.6 and 10 mg ai/l). 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 (92-106% of nominal) and thus nominal concentrations were used. Temperature: 12.6-14.5°C. pH 7.6-8.2. Dissolved oxygen 7.6-8.3 mg/L. Standards and test solutions were tested by HPLC employing an external standard.

RESULTS

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

1.0	10	0	0	0	0	0	0
1.8	10	0	0	0	0	0	0
3.2	10	0	0	0	0	0	0
5.6	10	0	1	5	6	6	6
10	10	10	10	10	10	10	10

LC50	5.3 mg/L at 96 hours (95% confidence level of 4.5-6.3 mg/L).
NOEC (or LOEC)	3.2 mg/L at 96 hours.
Remarks – Results	No mortalities were observed at test concentrations of less than 3.2 mg/L. After 96 h, 60 and 100% mortality was observed at test concentrations of 5.6 and 10 mg/L respectively. A sub-lethal effect was observed at the test concentration of 5.6 and 10 mg ai/L. This response was the presence of a moribund fish after 1 h and 40 min exposure at 10 mg ai/L, and after 29 h and 30 min exposure at 5.6 mg ai/L.
CONCLUSION	The ecotoxicity data indicates the notified chemical is acutely toxic to rainbow trout.
TEST FACILITY	SPL (2003j)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation 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 notified chemical was stable during the tests.
Remarks - Method	Range-finding and definitive tests were performed. At concentrations of 0.01, 0.10, 1.0 and 10 mg ai/L no immobilisation was observed, however, 80% immobilisation was observed at 100 mg ai/L after 48 h exposure. Subsequently, test concentrations 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		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
1.8	1.84	10	0	0
3.2	3.21	10	0	0
5.6	5.68	10	0	0
10	10.1	10	0	0
18	16.8	10	0	0
32	34.4	10	0	2
56	55.7	10	0	3
100	102	10	2	8
180	162	10	3	10

EC50	60 mg ai/L at 48 hours (95% confidence level of 51-72 mg ai/L)
NOEC (or LOEC)	18 mg ai/L at 48 hours
Remarks - Results	No effects were observed at test concentrations of less than 18 mg/L. These solutions were clear and pink while those greater than 18 mg/L were clear red solutions of increasing colour density. After 48 h, 50 % of the population showed effects at the nominal test concentrations of 60 mg ai/L of the notified substance, with a 95% confidence limit.

CONCLUSION	The ecotoxicity data indicates the notified chemical is harmful to *Daphnia magna*.
TEST FACILITY	SPL (2003k)

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	3.2, 10, 32, 100, 320 mg/L
Auxiliary Solvent	None
Analytical Monitoring	Standards and test solutions were tested by HPLC. These were 85-92% 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 $9.47x10^3$ cells/mL (initial) and $4.80x10^5$ cells/mL (72 hours). Mean cell density in Expt. B was $8.19x10^3$ cells/mL (initial) and $3.93x10^5$ 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	28 mg ai/L	2.6 mg ai/L	200 mg ai/L
B	43 mg ai/L	10 mg ai/L	94 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 notified chemical on algal growth was not only due to a reduction in light intensity, but also due to the intrinsic toxic properties of the chemical. Therefore, for classification purposes the results determined from Experiment A should be used.
CONCLUSION	The results indicated the combined toxic nature of the notified chemical and the effects of reduction in light intensity.
TEST FACILITY	SPL (2003l)

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	Activated sewage
Exposure Period	3 hours
Concentration Range Nominal	10-3200 mg/L
Remarks – Method	Following a preliminary range-finding test, activated sludge was exposed in the definitive test to an aqueous solution of the test material at concentrations of 10, 32, 100, 320, 1000 and 3200 mg/L 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	>3200	160
Reference	22	13
Variation in respiration rate of controls 1 and 2	±2%	±7%

EC50	160 mg/L (3 hour)
NOEC	10 mg/L (3 hour)
Remarks – Results	The validation criteria for the control respiration rates and reference material EC50 values were satisfied. In some instances, the initial and final dissolved oxygen concentrations were below those recommended in the test guidelines. However, this was considered to have no adverse effect on the results given.

CONCLUSION The effect of the notified chemical on the respiration of activated sludge micro-organisms gave a 3-hour EC50 of 160 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 10 mg/L.

TEST FACILITY SPL (2003m)

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 readily 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.

Incineration of waste paper and sludges will destroy the notified chemical 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 (WWTP). 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 and 50% of

this in the supernatant effluent discharged to sewer (assuming no WWTP attenuation and a discharge of 1% of the Australian total wastewater flow of $1.46x10^{12}$ L/annum), the predicted environmental concentration (PEC) of the notified chemical would be <0.017 mg/L.

Although it is not considered to be readily biodegradable, significant biodegradation of the notified chemical is expected to occur over time. 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 available ecotoxicological data indicate the notified chemical is acutely toxic to fish and harmful to *Daphnia magna*. The most sensitive species are fish, where the 96-hour LC50 is 5.3 mg/L and the NOEC was 3.2 mg/L. Acute results are available for 3 trophic levels. Applying an assessment factor of 100 to the most sensitive species (fish), the predicted no effect concentration (PNEC) is 53 μg/L.

It is however expected, that there will be minimal release to water. In addition, bioaccumulation is not expected due to the notified chemical's low log Pow, implying low lipid solubility, and large molecular weight (range 1208 - 1272 g/mol), which inhibits passage through cell membranes.

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 low imported volume of ≤1 tonnes per year, 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 is 0.32 (assuming a worst case), indicating moderate risk to the aquatic compartment. However, 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 risk 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

Printer cartridges are sealed and worker exposure to the ink is minimised by following the manufacturers' instructions on handling, replacing and disposing ink cartridges. Exposure by inhalation is expected to be negligible due to the physicochemical nature of the notified chemical such as high molecular weight, low vapour pressure and high water solubility.

For routine handling of ink cartridges, the following precautions are recommended: (1) Avoid contact of ink with the eyes, skin and clothing; (2) Wash hands after use with soap and cold water. Office printers should be positioned in well-ventilated areas to avoid accumulation of any dusts, gases or fumes.

9.2.2. Public health – exposure assessment

The notified chemical will be imported in prepacked cartridges. Dermal exposure to the notified chemical may occur infrequently when replacing spent cartridges and handling printed papers. However, the concentration of the notified chemical in the ink is low, and the design of the cartridges is such that exposure to the notified chemical should be low.

9.2.3. Human health – effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg/bw). It is not irritant to rabbit skin, but shows sensitising activity at 25% solution in a local lymph node assay (LLNA). It is severely irritating to the rabbit eye. Red coloration of faeces and staining of perianal region were observed in all animals of the dose groups (60, 250 and 1000 mg/kg bw/day), however, no haemorrhage from the digestive tract or changes in the bone

marrow were seen at necropsy. The NOAEL was established to be 250 mg/kg bw/day in a 28-day repeated dose oral study in rats, based on haematology and clinical chemistry. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

Based on the available toxicological data, the notified chemical can cause severe irritation and staining of the eyes. However, the risk of eye irritancy is low given the packaging of the ink cartridges and workers are advised to avoid eye and skin contact with the ink and observe general hygiene practices such as washing of hands after handling the cartridges. The risk of skin sensitisation is particularly low as contact should be intermittent and to small amounts. Although inhalation exposure to the ink is unlikely, office printer should be positioned in well-ventilated areas.

Up to hundred maintenance workers will be potentially exposed to the ink containing the notified chemical. However, they are adequately trained and wear disposable gloves to minimise the skin exposure. In addition, spillage is unlikely because of the fully enclosed ink cartridges. Personnel involved in cleaning-up of spills should protect themselves against respiratory, skin and eye exposure.

9.2.5. Public health – risk characterisation

There should be a low risk of eye irritancy or skin sensitisation to the public on exposure through changing ink cartridges and handling printed materials containing the notified chemical given the intermittent and low exposure and the low concentration of the notified chemical in the ink.

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

10.1. Hazard classification

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

R41 - Risk of serious damage to eyes
R43 - May cause sensitisation by skin contact

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), and skin sensitisation (category 1).

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 in the proposed manner.

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 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 notified 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
  - R43 - May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - $\geq$ 10%: R41 - Risk of serious damage to eyes
  - 10% $\geq$ conc $\geq$ 5%: R36 - Irritating to eyes

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the ink cartridges containing the notified chemical:
  - Adequate induction and training programs for printer service engineers.
  - Printers should be positioned in well-ventilated areas.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in ink cartridges:
  - Wearing cotton or disposable gloves during maintenance 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 should be incinerated, recycled or sent to landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained and collected mechanically (eg with absorbent material or sweeping dried material). Avoid rasing dust. Do not allow material to contaminate ground water system. 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(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

Ishidate M (1987). *Mutagens and Toxicity*, 4:64-73.

ME (2002a) Mutagenicity study of 01433 [notified chemical] in microorganisms. Study no. M-02010. Kanagawa, Japan, Material Safety Test Center, Environmental Protection & Products Safety Division, Fuji Photo Film Co., Ltd (unpublished report submitted by the notifier).

ME (2002b) Chromosome aberration study of 01433 [notified chemical] in cultured mammalian cells. Study no. A-02012. Kanagawa, Japan, Material Safety Test Center, Environmental Protection & Products Safety Division, Fuji Photo Film Co., Ltd (unpublished report submitted by the notifier).

ME (2003) Biodegradability study of 01433 [notified chemical]. Study no. B-02022. Kanagawa, Japan, Material Safety Test Center, Environmental Protection & Products Safety Division, Fuji Photo Film Co., Ltd (unpublished report submitted by the notifier).

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.

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

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

Saitama Laboratory (2002) Twenty-eight day repeated dose oral toxicity study on [FYS-109] in rats. Study no. 0231-2. Saitama, Japan, Saitama Laboratory, Drug Safety Testing Center Co., Ltd (unpublished report submitted by the notifier).

SPL (2003a) FYS-109: Determination of general physico-chemical properties (Annex VIIB). Project no. 1307/160. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003b) FYS-109: Determination of general physico-chemical properties. Project no. 1307/173. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003c) FYS-109: Determination of hazardous physico-chemical properties. Project no. 1307/174. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003d) FYS-109: Determination of flammability (solids). Project no. 1307/161. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003e) FYS-109: Acute oral toxicity in the rat – Acute toxic class method. Project no. 1307/162. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003f) FYS-109: Acute dermal toxicity (limit test) in the rat. Project no. 1307/163. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003g) FYS-109: Acute dermal irritation. Project no. 1307/164. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003h) FYS-109: Acute eye irritation in the rabbit. Project no. 1307/165. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

SPL (2003i) FYS-109: Local lymph node assay in the mouse. Project no. 1307/310. Derbyshire, UK, SafePham Laboratories Limited (unpublished report submitted by the notifier).

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.