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6 October 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C-SR

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd (ABN 66 005 002 951)
1 Thomas Holt Drive
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:

Chemical Name
Other Name(s)
CAS Number
Molecular Formula
Structural Formula
Molecular Weight
Spectral Data
Purity
Impurities
Additives/Adjuvants
Introduction Volume

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

Spectral Data
Dissociation Constant
Flash Point
Explosivity
Reactivity
Acute Inhalation Toxicity
Induction of Germ Cell Damage
Daphnia sp. Acute Immobilisation/Reproduction
Bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC Permit No. 644 (File No. LVC/659) 2004

NOTIFICATION IN OTHER COUNTRIES
Notified worldwide 2004-2005

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
C-SR
JPD Cyan C-SR
JPD Cyan C-SR Liquid
Substituted phthalocyanine dye

SPECTRAL DATA

METHOD Ultra-Violet/Visible and Infrared spectra
Remarks Reference spectra were provided

METHODS OF DETECTION AND DETERMINATION

METHOD High Performance Liquid Chromatography
Remarks A reference trace was provided

3. COMPOSITION

DEGREE OF PURITY
>90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
No hazardous impurities above cut-off concentrations for classification.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported from overseas as a component of inkjet printer ink, contained within ink cartridges.

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

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

USE
The notified chemical will be a component (0.5-7%) of inkjet printer ink. The notified chemical acts as a dyestuff for the ink.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney Airport or Sydney Harbour

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will not be manufactured or reformulated in Australia.

TRANSPORTATION AND PACKAGING
Sealed ink cartridges containing printer ink (0.5-7% notified chemical) will be transported by land and stored in warehouses prior to distribution to customers.

5.2. Operation description

The notified chemical is imported from overseas as a component of printer ink contained in a sealed cartridge packaged in cardboard cartons.

The cartridges will be transported and stored prior to national distribution where they will be sold to consumers for replacement in printers at home and in the office. The only operation that end users will perform is to replace the ink cartridge in a printer. The cartridges will be replaced either by office workers, service technicians or consumers. The ink containing 0.5-7% notified chemical is contained within the cartridge. To change the cartridge, the seal tape is removed and the cartridge is placed into the printer.

During the printing process, the ink turns into an extremely fine mist that is transferred to the paper.

5.3. Occupational exposure

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Importation/Storage/Transport	Tens	<8	10-50 days/year
Office Workers	Thousands	<1	2 days/year
Service Technicians	Tens	1	170

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

Office workers may be intermittently exposed to the notified chemical when replacing the spent cartridge Printer maintenance workers may be intermittently exposed to the notified chemical during maintenance and cleaning of printers. Dermal exposure is the most likely route. Dermal exposure is also possible from contact with printed paper before the ink has dried, and from contact with incorrectly used non-absorbent substrates such as overhead films.

Exposure is expected to be controlled through the design of the ink cartridge and of the printer. Printer maintenance personnel often wear cotton disposable gloves. Ink cartridges are sealed until use and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer. Once dried, the ink will be bound to the paper and no longer biologically available, except in the case of incorrectly used non-absorbent substrates such as overhead films, which will be discarded.

Inhalation exposure is possible from the fine mist of ink produced during the printing process. However, the ink mist is designed to be localised and to adhere to the paper with little release from the printer, and the notified chemical has a very low vapour pressure and a small proportion of respirable particles.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Printer ink is imported in ready-to-use cartridges of 2 to 150 mL (containing < 7% 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. If there is a transport accident the individual container capacity, and container and packaging specifications would limit the extent of release to the environment.

RELEASE OF CHEMICAL FROM USE
Cartridges will be changed by office staff and the general public. Release of ink solution to the environment is not expected under normal use as ink cartridges are designed to prevent leakage. However, if leakage or spillage does occur, the ink will be contained with absorbent material, which will presumably be disposed of in landfill.

Ultimately, the majority of the notified chemical will suffer the same fate as the paper to which it is bound. This will either be disposal to landfill, or incineration or recycling. Residues (up to 5%) 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 or recycled. The sludge from the deinking process will be disposed of to landfill.

While some of the empty cartridges will be recycled, the majority will be disposed of to landfill, accounting for up to 150 kg of notified chemical annually.

5.6. Public exposure

The public may intermittently be exposed to the notified chemical when replacing the spent cartridge, and during maintenance and cleaning of home printers. Dermal exposure is the most likely route. Dermal exposure is also possible from contact with printed paper before the ink has dried.

Exposure is expected to be controlled through the design of the ink cartridge and of the printer. Ink cartridges are sealed until use and exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer. Once dried, the ink will be bound to the paper and no longer biologically available.

Inhalation exposure is possible from the fine mist of ink produced during the printing process. However, mist emission of ink from printers is expected to be low, and the notified chemical has a very low vapour pressure and a small proportion of respirable particles.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa The notified chemical is a purple crystalline solid. The imported ink is a cyan liquid.

Melting Point/Freezing Point >377ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. USA, EPA OPPTS Method 830.7200 Melting Point/Melting Range
Remarks	Scanning calorimetry method. Decomposed at 377°C before melting.
TEST FACILITY	Safepharm (2004a)

Boiling Point Not determined.

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Not applicable as the notified chemical decomposed before melting.
TEST FACILITY	Safepharm (2004a)

Density 1763 kg/m^3 at 20ºC

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density. USA, EPA OPPTS Method 830.7300 Density/Relative Density/Bulk Density
Remarks	Gas comparison pycnometer method.
TEST FACILITY	Safepharm (2004a)

Vapour Pressure 4 x 10^{-13} kPa at 25ºC

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure. US, EPA OPPTS Method 830.7950 Vapor Pressure.
Remarks	The vapour pressure balance method was used over an approximately 17 ¾ hour period and a temperature range of 230 to 240ºC.
TEST FACILITY	Safepharm (2004b)

Surface Tension 72.5 mN/m at 22±0.5ºC

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

Remarks Measurements were taken at intervals until a constant reading was obtained using an interfacial tension balance.

This result indicates that the notified substance is not surface active.

TEST FACILITY Safepharm (2004a)

Water Solubility 34.2-36.2% (w/w) at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
USA, EPA OPPTS Method 830.7840 Water Solubility: Column Elution Method; Shake Flask Method.

Remarks Method variation: Due to high indeterminable saturation methods, it was not possible to prepare samples at five times the saturation level as recommended in the guidelines. Analysis could not be performed because of the gel-like, viscous mixtures produced at high solubility levels. Therefore water solubility was determined based on visual inspection.

This result indicates that the notified substance is readily water soluble (Mensink, 1995).

TEST FACILITY Safepharm (2004a)

Hydrolysis as a Function of pH Hydrolytically stable.

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

PH	*T (°C)*	*t½ (years)*
4	25	> 1
7	25	> 1
9	25	> 1

Remarks Aliquots (in duplicate) of sample solutions were taken at 0, 2.4, 24 and 120 hours and the pH of the solution was recorded. The concentration of the test substance was determined spectrophotometrically.

After 120 hours (5 days) at all pHs and at 50ºC it was found that less than 10% of the test substance had hydrolysed, indicating a half-life of greater than 1 year.

This indicates that the notified chemical is not likely to hydrolyse in the environment.

TEST FACILITY Safepharm (2004a)

Partition Coefficient (n-octanol/water) log Pow = <-3.66 at 22±0.5ºC

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

Remarks Shake Flask Method

Measured amounts of the test substance and water saturated n-octanol were shaken by inversion at 22ºC for 5 minutes at neutral pH and then centrifuged at 10000 rpm for 20 minutes. Aliquots of the water and n-octanol phases were taken for analysis by spectophotometry. Dimethylsulfoxide was used to dilute the samples. The n-octanol phase samples were diluted by a factor of 2, while the aqueous samples were diluted 100-fold.

This result indicates that the notified chemical is likely to favour the water phase.

TEST FACILITY Safepharm (2004a)

Adsorption/Desorption log Koc <1.25

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)

Remarks The HPLC screening method was used with 12 reference standards of known adsorption coefficients. The retention time of the test substance was 1.508 minutes which was less than that for acetanilide (4.001 minutes) which has a known log Koc of 1.25, therefore the log adsorption coefficient is less than 1.25.

The test was done at approximately neutral pH and therefore reflects the ionised substance.

This result indicates that the notified substance will be mobile in soils and sediments.

TEST FACILITY Safepharm (2004a)

Dissociation Constant Not determined.

Remarks Standard test methods are not applicable to substances with multiple pKa's, and due to the chemical nature of the substance computer modelling software could not be used. The notified chemical has strong acid functionalities, and will remain ionised throughout the environmental pH range of 4 to 9.

Particle Size

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

Range (μm)	*Mass (%)*
<100	38.6
<10	4.03

Remarks Sieve method for measuring particles <100μm.

Cascade impactor method for measuring particles <10μm.

TEST FACILITY Safepharm (2004a)

Flash Point Not determined.

Remarks Not applicable to a high melting point solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
USA, EPA OPPTS Method 830.6315: Flammability.

Remarks The negative result of the preliminary test obviated the need to perform the main test.

TEST FACILITY Safepharm (2004c)

Autoignition Temperature >400°C

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

Remarks None

TEST FACILITY Safepharm (2004b)

Explosive Properties Not expected to be explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties. US, EPA OPPTS Method 830.6316
Remarks	The notified chemical contains no chemical groups that would imply explosive properties, therefore the result has been predicted negative.
TEST FACILITY	Safepharm (2004b)

Oxidizing Properties Not expected to be oxidising.

METHOD	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	The notified chemical contains no chemical groups that would imply oxidising properties, therefore the result has been predicted negative.
TEST FACILITY	Safepharm (2004b)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 >2000 mg/kg bw low toxicity
Rat, acute dermal	LD50 > 2000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	severely irritating
Mouse, skin sensitisation – local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL= 150 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic in two separate studies
Genotoxicity – in vitro chromosomal aberration test	non genotoxic in two separate studies

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley (CD)
- Vehicle: Arachis oil BP
- Remarks - Method: A correction factor was applied to account for substance purity.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 females	2000	0/6

- LD50: >2000 mg/kg bw
- Signs of Toxicity: The only clinical sign observed was blue staining of faeces and urine. There were no signs of systemic toxicity.
- Effects in Organs: Dark liver in 3 females; dark grey liver in the remaining animals.
- Remarks - Results: None.

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

TEST FACILITY — SafePharm (2004d)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD — OEC D 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: Arachis oil BP
- Type of dressing: Semi-occlusive.
- Remarks - Method: A correction factor was applied to account for substance purity.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	0/10

- LD50: >2000 mg/kg bw
- Signs of Toxicity - Local: Turquoise staining at treatment sites but no signs of dermal irritation.

Signs of Toxicity - Systemic	Turquoise staining of faeces but no signs of systemic toxicity.
Effects in Organs	No abnormalities observed at necropsy.
Remarks - Results	None

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

TEST FACILITY — SafePharm (2004e)

7.3. Irritation – skin

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	None

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	1 hour	0
Oedema	0	0	0	0	-	0

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

Remarks – Results — Slight purple staining was observed at 2 treated skin sites. This did not affect evaluation of skin reactions.

Slight erythema was noted at 2 treated skin sites 1 hour after patch removal.

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

TEST FACILITY — SafePharm (2004f)

7.4. Irritation – eye

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Observation Period	21 days
Remarks - Method	None

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Conjunctiva: redness	0.67	2	48 hours	0
Conjunctiva: chemosis	0.33	2	24 hours	0
Conjunctiva: discharge	0.33	3	24 hours	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results: Blue staining of the conjunctival membrane and cornea of the treated eye, and of the fur around the treated eye, was observed throughout the study.

CONCLUSION: The notified chemical is severely irritating to the eye based on irreversible staining of the conjunctivae up to 21 days post-instillation.

TEST FACILITY: SafePharm (2004g)

7.5. 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/Ca
Vehicle: Dimethyl formamide
Remarks - Method: None

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	596.42	-
1	496.65	0.83
2.5	404.49	0.68
5	521.39	0.87

Remarks - Results: Blue coloured staining was observed around the ears.

Historical positive control data were referred to. The latest positive control study referred to demonstrated the sensitivity of the assay to alpha-hexylcinnamaldehyde.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: SafePharm (2004h)

7.6. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
USA EPA Health Effects Test Guidelines, OPPTS 870.3050 Repeated Dose 28-Day Oral Toxicity Study in Rodents
Japanese MHW Guidelines 1986 for a Twenty-Eight Days Repeat Dose Oral Toxicity Study
Species/Strain: Rat/Sprague-Dawley Crl:CD

Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days (control and high dose only)
Vehicle	Distilled water
Remarks - Method	Dose levels were selected based on the results of a range finding study and were adjusted for the purity of the test substance.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	25	0/10
III (mid low dose)	5/sex	150	0/10
IV (mid high dose)	5/sex	300	0/10
V (high dose)	5/sex	1000	0/10
VI (control recovery)	5/sex	0	0/10
VII (high dose recovery)	5/sex	1000	0/10

Clinical Observations

Blue or dark staining of fur and/or faeces was observed in animals of either sex treated with 1000 or 300 mg/kg bw/day. This was considered to be associated with administration and excretion of coloured test material and, in the absence of any other treatment related effects, not indicative of toxicity.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment related effects were observed for clinical chemistry or haematology parameters.

Blue/green urine was observed in animals of either sex treated with 1000, 300 or 150 mg/kg bw/day. This was considered to be normal excretion of coloured test material and, in the absence of any other treatment related effects, not indicative of toxicity.

Effects in Organs

Recovery high dose males had statistically significantly lower relative kidney and liver weights, and absolute testes weights. No similar effects were observed in non-recovery high dose animals.

Discolouration was observed in the majority of tissues in animals of either sex treated with 1000 mg/kg bw/day, and in the kidneys, gastro-intestinal tract and lungs of animals treated with 300 or 150 mg/kg bw/day. Recovery high dose animals also showed this effect. The effect was considered a result of oral administration of coloured test material, and not an adverse health effect.

The following treatment related histopathological changes were observed:

Hepatocyte enlargement was observed in males treated with 1000 or 300 mg/kg bw/day. Associated eosinophilic intracytoplasmic inclusions were also observed in some high dose males. Females were not similarly affected. The condition had regressed among recovery high dose males.

Agglomeration of secretion was observed in the gastric mucosa of animals of either sex treated with 1000 or 300 mg/kg bw/day. Occasional instances were also observed in animals treated with 150 or 25 mg/kg bw/day, but in the absence of a dose response this was not considered convincing evidence of treatment related toxicity.

Remarks – Results

None

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in this study, based on hepatocyte enlargement and agglomeration of secretion in the gastric mucosa of animals treated with 300 mg/kg bw/day.

TEST FACILITY SafePharm (2004i)

7.7.1. Genotoxicity – bacteria (I)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2*uvr*A$^-$
Metabolic Activation System	phenobarbitone/β naphthoflavone induced 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	Distilled water
Remarks - Method	None

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	None observed	None observed	None observed	None observed
Test 2		None observed	None observed	None observed
Present				
Test 1	None observed	None observed	None observed	None observed
Test 2		None observed	None observed	None observed

Remarks - Results All of the positive controls induced marked increases in the frequency of revertant colonies. Negative controls were within expected ranges.

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

TEST FACILITY SafePharm (2004j)

7.7.2. Genotoxicity – bacteria (II)

TEST SUBSTANCE Notified chemical

METHOD Not specified.

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2*uvr*A (pKM101)
Metabolic Activation System	Phenobarbital and 5,6-Benzoflavone induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 0.1953-50 µg/plate b) Without metabolic activation: 0.1953-50 µg/plate
Vehicle	Sterilised water
Remarks - Method	Similar to OECD TG 471 Bacterial Reverse Mutation Test, plate incorporation method.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	None observed	None observed	None observed	None observed
Present	None observed	None observed	None observed	None observed

Remarks - Results	All of the positive controls induced marked increases in the frequency of revertant colonies. Negative controls were within expected ranges.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Canon Inc. (2004a)

7.8.1. Genotoxicity – in vitro (I)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese hamster lung (CHL) cells
Metabolic Activation System	Phenobarbitone and beta-naphthoflavone induced rat liver S9 fraction
Vehicle	Minimal Essential Medium (MEM)
Remarks - Method	None

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 39.06, 78.13, 156.25*, 312.5*, 468.75*, 625	6	24
Test 2	0*, 39.06*, 78.13*, 156.25*, 312.5, 468.75, 625	24	24
Present			
Test 1	0*, 156.25, 312.5*, 625*, 1250*, 1875, 2500	6	24
Test 2	0*, 156.25, 312.5*, 625*, 1250*, 1562.5, 1875	6	24

*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	19.53	All concentrations	None observed	None observed
Test 2		All concentrations	None observed	None observed
Present				
Test 1	19.53	All concentrations	None observed	None observed
Test 2		All concentrations	None observed	None observed

Remarks - Results	The maximum dose selected for metaphase analysis was based on toxicity: at higher doses there were insufficient metaphases to score due to toxicity of test material. Positive controls induced statistically significant increases in the frequency of cells with aberrations. Vehicle controls were within historical ranges.
CONCLUSION	The notified chemical was not clastogenic to CHL cells treated in vitro under the conditions of the test.
TEST FACILITY	SafePharm (2004k)

7.8.2. Genotoxicity – in vitro (II)

TEST SUBSTANCE	Notified chemical

METHOD	Not specified
Cell Type/Cell Line	Chinese hamster lung (CHL) cells
Metabolic Activation System	Phenobarbital and Benzoflavone induced rat liver S9 fraction
Vehicle	0.9% saline
Remarks - Method	Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	39, 78, 156, 313, 625, 1250*, 2500*, 5000*	6	24
Test 2	39, 78, 156, 313*, 625*, 1250*, 2500, 5000	24	24
	39, 78*, 156*, 221, 313*, 442, 625, 1250, 2500, 5000	48	48
Present			
Test 1	39, 78, 156, 313, 625, 1250*, 2500*, 5000*	6	24

*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	All concentrations	All concentrations	None observed	None observed
Test 2 – 24 hours		All concentrations	None observed	None observed
Test 2 – 48 hours		All concentrations	None observed	None observed
Present	All concentrations	All concentrations	None observed	None observed

Remarks - Results	Metaphase cells at 2500 μg/mL and higher for 24-hour exposure, and at 625 μl/mL and higher for 48-hour exposure, were not analysable due to cytotoxicity of the test material. Positive controls induced statistically significant increases in the frequency of cells with aberrations. Vehicle controls were within historical ranges.
CONCLUSION	The notified chemical was not clastogenic to CHL cells treated in vitro under the conditions of the test.
TEST FACILITY	Canon Inc. (2004b)

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).

Method of testing the biodegradability of chemical substances by microorganisms, in Testing methods for new chemicals substances, July 13, 1974, No 5 Planning and Coordination Bureau, Environment Agency.

Inoculum	Activated sludge – city plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biological Oxygen Demand (BOD) by Closed system oxygen consumption measurement – soda lime. TOC HPLC
Remarks - Method	Reference substance – aniline Concentration of suspended solids – 3700 mg/L Treatments: - water + test substance – 100 mg/L – vessel 1 - sludge + test substance – 100 mg/L – vessels 2, 3 and 4 - sludge + aniline – 100 mg/L – vessel 5 - control blank – activated sludge only – vessel 6 - Temperature measured daily – 25°C BOD was measured by data sampler and autorecorder. At termination the dissolved organic carbon, test substance concentration and pH were measured.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	52
14	0	14	73
21	0	21	75
28	1	28	76

Percentage biodegradation via different methods – ONLY in test solutions (Vessels 2, 3 & 4)				
Method	% degradation			
	Vessel 2	Vessel 3	Vessel 4	Average
BOD	1	0	1	1
TOC	9	3	4	5
HPLC	2	1	0	1

Remarks - Results: None

CONCLUSION: Under the study conditions the notified chemical was not readily biodegradable.

TEST FACILITY: Kurume (2004)

8.1.2. Bioaccumulation

Not determined. However, the notified chemical is not likely to bioaccumulate based on its very low log P_{ow}.

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 conditions. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - semi-static conditions.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometry
Remarks – Method	Based on range-finding tests it was determined that a limit test at 100 mg/L would be done. A measured amount of test substance was dissolved in water by ultrasonication for 10 minutes. The test solution was a blue colour. The concentration and stability of the test solution was determined at 0, 24 and 96 hours. The test vessels, each with 10 fish, were covered, maintained at 14ºC, exposed to a photoperiod of 16 hours light/8 hours dark and aerated throughout the study. Temperature, pH and dissolved oxygen were recorded daily. Test solution was renewed daily. Observations were made at 3, 6, 24, 48, 72 and 96 hours with the fish being transferred to clean water for the observations.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	-	20	0	0	0	0	0
100	88.3-91.8	20	0	0	0	0	0

LC50	>100 mg/L nominal at 96 hours.
NOEC	100 mg/L nominal at 96 hours.
Remarks – Results	No sublethal effects were observed in the fish throughout the study. All environmental parameters were within acceptable ranges.
CONCLUSION	Under the study conditions the test substance is very slightly toxic to fish (Mensink, 1995).
TEST FACILITY	SafePharm (2004l)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – static conditions. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static conditions.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L

Analytical Monitoring	Spectrophotometry
Remarks - Method	After a range finding test, test concentrations (1, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100 mg/L) were chosen. Test solutions were blue in colour with increasing colouration with increasing concentration. The concentrations 1, 3.2, 10 32 and 100 were analysed for concentration verification and stability at 0 and 48 hours. The test vessels, each with 10 daphnia, were covered, maintained at 21ºC, exposed to a photoperiod of 16 hours light /8 hours dark and were not aerated throughout the study. Temperature was recorded daily, while pH and dissolved oxygen were recorded at the start and end of the study. Observations were made at 24 and 48 hours. At the three highest concentrations the daphnia were transferred to clean water for the observations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
1.0	0.914	20	0	0
1.8	-	20	0	0
3.2	2.81	20	0	0
5.6	-	20	0	0
10	8.79	20	0	0
18	-	20	0	0
32	28.2	20	0	5
56	-	20	0	12
100	90.0	20	0	20

LC50	46 mg/L nominal at 48 hours
NOEC	18 mg/L nominal at 48 hours
Remarks - Results	No sublethal effects were observed in the daphnia throughout the study. All environmental parameters were within acceptable ranges.

CONCLUSION — Under the study conditions, the notified chemical is harmful to aquatic invertebrates (United Nations, 2003).

TEST FACILITY — SafePharm (2004m)

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	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0, 3.2, 10, 32, 100 and 320 mg/L Actual: 0.9, 2.91, 8.91, 27.9, 94.4 and 294 mg/L at 0 hours Actual: 1.53, 3.26, 9.44, 28.8, 96.4 and 303 mg/L at 72 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Spectrophotometry
Remarks - Method	Two experimental methods were conducted in parallel to determine whether the growth effects were due to toxicity or light intensity. Both used test concentrations of 1.0, 3.2, 10, 32, 100 and 320 mg/L, constant illumination and stirring, and temperature maintained at 24±1 °C. Experiment A: 3 replicates per concentration. Algae were exposed to test material in a flask enclosed from above by a petri dish containing culture

medium only. Inhibition was therefore due to a combination of toxicity and reduction in light intensity.

Experiment B: 2 replicates per concentration. 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.

RESULTS

Experiment A: Growth			*Experiment B: Growth*		
E_bC_{50} *mg/L at 72 h*	E_rC_{50} *mg/L at 72 h*	*NOEC mg/L*	E_bC_{50} *mg/L at 72 h*	*ErC50 mg/L at 72 h*	*NOEC mg/L*
21 95% CI 16-28 mg/L	190	1.0	15 95% CI 12-19 mg/L	46 95% CI 35-60 mg/L	1.0

Remarks - Results

Test solutions from experiment A were analysed to confirm concentration. Test concentrations ranged from 87 to 115% of the nominal concentration.

The inhibition of growth was greater in Experiment B, therefore it was determined that the effect was due to light intensity rather than a toxic effect due to the test substance.

CONCLUSION

Under the study conditions, the test material did not inhibit algal growth other than by the reduction of light intensity.

TEST FACILITY

SafePharm (2004n)

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 sludge from a domestic STP
Exposure Period: 3 hours
Concentration Range: Nominal: 1000 mg/L
Remarks – Method: From a range finding test, it was determined that only one test concentration needed to be used – 1000 mg/L. The study was conducted in triplicate. Vessels were aerated during the tests, and O_2 consumption rates were monitored. Temperature was maintained at 21°C. Duplicate controls were run in parallel.

Reference substance – 3,5-dichlorophenol

Rate of respiration was determined after 30 minutes and 3 hours contact.

Total water hardness – 100 mg/L $CaCO_3$.

RESULTS

EC50: >1000 mg/L
NOEC: 1000 mg/L
Remarks – Results: Reference substance 3 h EC_{50} = 10 mg/L

The validity criteria for control respiration rates variation and reference material toxicity were satisfied.

	Environmental parameters were within acceptable ranges.
CONCLUSION	Under the study conditions the notified chemical is not toxic to micro-organisms.
TEST FACILITY	SafePharm (2004o)

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 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. Waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the compound. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, nitrogen and sulphur plus sodium and copper salts.

Emptied ink cartridges containing a residue of notified chemical will be sent to landfill for disposal. In a landfill, the notified chemical is expected to be immobile, and eventually it will degrade through biotic and abiotic processes. Consequently, there should not be significant exposure of the environment to the notified chemical.

Approximately 50% of the printed paper will enter the recycling process. During the recycling process, waster paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of the paper. Due to its high water solubility, a predicted environmental concentration (PEC) can be estimated assuming 50% of the total imported notified chemical enters recycling, of which 50% (ie 25% of imported volume) will remain in the supernatant effluent discharged to sewer (assuming no WWTP attenuation). The predicted environmental concentration (PEC) of the notified chemical would be:

Amount in effluent entering sewer	750 kg
Number of days	365
National population	20 million
Litres per person per day	200 L
PEC_{sewer}	0.5 μg/L.

9.1.2. Environment – effects assessment

The ecotoxicological data indicate the notified chemical is harmful to aquatic invertebrates, slightly toxic to fish and not toxic to algae other than by reduction of light intensity. The most sensitive species is Daphnia, for whom the 48-hour LC50 is 46 mg/L. Acute results are available for 3 trophic levels, so it is appropriate to apply an assessment factor of 100 to the most sensitive species (Daphnia), thus the predicted no effect concentration (PNEC) is 460 μg/L.

The notified chemical is not readily biodegradable or hydrolysable and may persist in the aquatic environment until degraded by abiotic and biotic processes. Due to its low log Pow and high molecular weight it is not likely to bioaccumulate.

9.1.3. Environment – risk characterisation

A PEC/PNEC ratio of 0.001 (0.5/460) for aquatic ecosystems via sewer discharge indicates a low environmental risk.

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

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are

accidentally breached.

Office workers and printer maintenance workers may be intermittently exposed to the notified chemical when replacing spent cartridges.. Service personnel are anticipated to have the greatest level of exposure. Exposure would be principally by skin contact. Inhalation exposure could also occur, particularly in the event of a spill.

Exposure to the notified chemical is, however, expected to be low due to the design of the cartridges and the low concentration (up to 7%) of the notified chemical in the printer ink. Exposure will be minimised by placing printers in areas of adequate ventilation and the use of disposable gloves by service personnel.

Exposure to the notified chemical from printed paper is expected to be negligible, as, once dried, it will be bound to the paper. Some intermittent exposure may occur if the ink is mistakenly printed onto a non-absorbent substrate.

9.2.2. Public health – exposure assessment

From the point of importation to the end use of the ink containing the notified chemical, the ink is either enclosed in a cartridge made for insertion in ink jet printers or is present on printed paper in a cured state. Public exposure through importation, transportation or storage is expected to be negligible. There is little potential for exposure during cartridge changes. Any exposure to the ink preparation that does occur is most likely to be dermal and of a minimal and transient nature. Ink containing the notified chemical on the printed page is bound to the paper and is not biologically available. Some intermittent exposure may occur if the ink is mistakenly printed onto a non-absorbent substrate. Overall, public exposure is expected to be low.

9.2.3. Human health – effects assessment

The notified chemical has a molecular weight only slightly less than 1000 and a low octanol/water partition coefficient, indicating a low degree of lipophilicity and low potential to cross biological membranes.

The notified chemical was of low acute oral and dermal toxicity to rats. Inhalation toxicity data were not submitted; however, the notified chemical has a low vapour pressure and a small proportion of respirable particles, indicating limited potential for inhalation.

The notified chemical was not irritating to rabbit skin and severely irritating to the rabbit eye, based on irreversible staining of the conjunctivae. There was no evidence of sensitisation to the notified chemical in a mouse local lymph node assay (LLNA).

The notified chemical was not mutagenic to bacteria, nor clastogenic to Chinese hamster lung cells, in replicated *in vitro* tests.

In a 28 day repeat dose oral toxicity study in rats, the No Observed Adverse Effect Level (NOAEL) was found to be 150 mg/kg bw/day, based on hepatocyte enlargement and agglomeration of secretion in the gastric mucosa of animals treated with a higher dose.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) and assigned the following risk phrases:

Xi Irritant
R41 Risk of serious damage to eyes

The notifier provided an additional primary eye irritation study for the ink product Cyan Ink Cartridge, containing 1-7% notified chemical. The product was found to be not irritating to the eyes of rabbits.

9.2.4. Occupational health and safety – risk characterisation

The risk to workers presented by the notified chemical is expected to be low given that the notified chemical is present in ink formulations at up to 7%, the ink is contained in enclosed cartridges, and printer maintenance personnel wear gloves.

9.2.5. Public health – risk characterisation

The public health risk presented by the notified chemical is expected to be low given that the notified chemical is present in ink formulations at up to 7%, and the ink is contained in enclosed cartridges.

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:

Xi Irritant
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.

	Hazard category	***Hazard statement***
Serious eye damage/eye irritation	1	Causes serious eye damage
Chronic hazards to the aquatic environment	3	Harmful to aquatic life with long lasting effects

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as a component of inkjet ink enclosed in cartridges.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the ink product containing 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 ink product 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:
  - Xi Irritant
  - R41 Risk of serious eye damage

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥10%:
    - Xi Irritant
    - 41 Risk of serious eye damage
  - 10%> conc ≥5%
    - Xi Irritant
    - R36 Irritating to eyes

CONTROL MEASURES
Occupational Health and Safety

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified chemical and during maintenance and repair.

- 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 office staff and others to minimise environmental exposure during use of the notified chemical:
  - Use in controlled environment with no drains in the immediate area.

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(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

Canon (2004a) Report of Mutagenicity Test Using Microorganisms, Report No. 693, Canon Inc., Tokyo, Japan (unpublished report provided by the notifier)

Canon (2004b) C-SR Metaphase Analysis in CHL Cells In Vitro, Report Number: C052, Canon Inc., Tokyo, Japan (unpublished report provided by the notifier)

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides. National Institute of Public Health and Environmental Protection Bilthoven, The Netherlands.

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 (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. 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.

Safepharm (2004a) C-SR: Determination of General Physico-Chemical Properties, SPL Project Number 345/702, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004b) C-SR: Determination of Hazardous Physico-Chemical Properties, SPL Project Number 345/703, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004c) C-SR: Determination of Flammability (Solids), SPL Project Number 345/704, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004d) C-SR: Acute Oral Toxicity in the Rat – Acute Toxic Class Method, SPL Project Number 345/705, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004e) C-SR: Acute Dermal Toxicity (Limit Test) in the Rat, SPL Project Number 345/706, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004f) C-SR: Acute Dermal Irritation in the Rabbit, SPL Project Number 345/707, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004g) C-SR: Acute Eye Irritation in the Rabbit, SPL Project Number 345/708, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004h) C-SR: Local Lymph Node Assay in the Mouse, SPL Project Number 345/709, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004i) C-SR: Twenty-Eight Day Repeated Dose Oral (Gavage) Toxicity Study in the Rat, SPL Project Number 345/710, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004j) C-SR: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* and *Escherichia coli*, SPL Project Number 345/712, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004k) C-SR: Chromosome Aberration Test in CHL Cells *In Vitro*, SPL Project Number 345/711, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004l) C-SR: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*), SPL Project Number 345/713, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004m) C-SR: Acute Toxicity to *Daphnia magna*, SPL Project Number 345/714, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004n) C-SR: Inhibition of Algal Growth Caused By Coloured Test Substances, SPL Project Number 345/715, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided by the notifier).

Safepharm (2004o) C-SR: Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge, SPL Project Number 345/716, Safepharm Laboratories Limited, Derbyshire, UK (unpublished report provided 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.Paste text here