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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C-FG-P

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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:
Part B: 1(a) Chemical name, (d) CAS number, (e) Molecular formula, (e) Structural formula, (f) Molecular weight, (g) Spectral data, 2(a) Purity, (c) Non-hazardous impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: 7(a) Manufacturing process, 9(h) Dissociation constant, 9(j) Flash point, 9(n) Reactivity
Part C: Acute Toxicity (c) Acute inhalation toxicity, Genetic Toxicity (h) Induction of germ cell damage, Ecotoxicity (k) *Daphnia* sp., acute immobilisation/reproduction

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Low volume chemical permit, 2004

NOTIFICATION IN OTHER COUNTRIES

United Kingdom	Annex VIIC notification, ref. 04-06-1759, July 2004 Annex VIIA notification, ref. 04-06-1759, August 2004
Switzerland	October 2004
USA	PMN No. P-04-0499, July 2004
Canada (Ontario)	June 2004
Japan	April 2005
Philippines	Code No. SQ1-2004-032, November 2004

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
C-FG-P (preferred marketing name in Australia), C-FG, JPD YELLOW C-FG, JPD YELLOW C-FG Liquid, Substituted stilbene sulfonic acid

3. COMPOSITION

DEGREE OF PURITY
>85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS

None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of inkjet printer ink. The ink is contained within print cartridges, with volumes between 2 and 150 mL.

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

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

USE
The notified chemical is a dyestuff for inkjet printer ink, present in inks at 0.5-7%. The inks will be used primarily by consumers and office workers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney Airport or Sydney Harbour

IDENTITY OF MANUFACTURER/RECIPIENTS
The ink cartridges will be stored at the notifier's warehouse before their distribution to offices and retailers of office supplies nationwide.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia as a component of inks contained in ready-to-use inkjet printer cartridges. There are a variety of different cartridges, within the following dimensions:

- Physical size: 12 x 20 x 15 mm to 70 x 30 x 120 mm
- Volume: 2 mL to 150 mL

After import, the cartridges are transported by land and are stored in a warehouse under cool, dry conditions, away from flames and sources of ignition. No safe transport or storage requirements apply (not a hazardous or dangerous good).

5.2. Operation description

Sealed inkjet cartridges containing the notified chemical are manufactured in Japan, and are imported intact. No reformulation, re-packaging, filling or re-filling of cartridges will take place within Australia, as the inkjet printer cartridges are an end-use packaging.

End-users (general public, office workers or service technicians) will remove the inkjet cartridge from its wrappings and use it to replace a spent cartridge in an inkjet printer as necessary. During the printing process, the printer turns the ink into an extremely fine mist, which is transferred to paper or other media in an automated fashion.

Used cartridges will primarily be disposed of to landfill or recycled.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (per day)*	*Exposure Frequency (per year)*
Importation/Dockside workers	50	< 8 hours	10-50 days
Storage and transport	15	< 8 hours	10-50 days
Office worker/consumer	2,000,000	10 seconds	2 days
Service technician	100	1 hour	170 days

Exposure Details

Dermal exposure is expected to be the main route of exposure. Inhalation exposure is unlikely, as the notified chemical is of low volatility in a liquid preparation. Ocular exposure is also expected to be unlikely, as the ink is only released in minute amounts within the confines of the printer.

Importation/dockside, storage and transport workers will only handle new, unopened cartridges containing the notified chemical. Therefore, exposure is highly unlikely unless the packaging and cartridges are accidentally breached.

The exposure of end-users of the inkjet printer cartridges (general public, office workers) is expected to be limited to dermal exposure. This would occur only if the wet ink was inadvertently touched, either while changing cartridges, from freshly printed media or if ink-stained parts of the printer were touched. Instructions on how to replace the cartridge safely are included with the cartridge, and reproduced on the inkjet printer. During the printing process, mist emission of the non-volatile components of the ink from the printer is expected to be low. Once the ink dries, the notified chemical would be trapped on the printed media, and therefore dermal exposure from contact with the dried ink is not expected.

Service technicians may be exposed to the ink (containing up to 7% notified chemical) during repair and cleaning of ink jet printers. Exposure is expected to be primarily dermal.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release of the notified chemical is expected, as no manufacturing or reformulation of the ink containing the notified chemical will take place in Australia. Inkjet printer ink is imported in ready-to-use cartridges of 2 to 150 mL (containing ink of <7% notified chemical). Environmental release of the notified chemical is unlikely during importation, storage and transportation. In the event of a transport accident, the individual container capacity, container and packaging specifications would limit the extent of release to the environment.

RELEASE OF CHEMICAL FROM USE

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

The majority of the notified chemical will undergo the same fate as the media on which it is printed. Environmental release of the notified chemical is possible from media (although no release is expected from printed paper) and from spent cartridges. Much of this will be disposed of to landfill.

Release is also possible during the recycling of both paper and cartridges. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. The notifier collects used, empty cartridges through collection boxes in general merchandising stores and post offices etc., and a subcontractor disassembles and recycles them for raw materials. Any remaining ink in these cartridges is washed out and disposed of through onsite wastewater treatment plants before being released to the sewer. Around 5% (by weight) of ink will remain in the “empty” cartridges, this results in a maximal release to the environment of 50 kg/year. Given that the use and disposal of the ink across Australia will be dispersed, the overall concentration predicted to enter the environment would be low.

5.5. Disposal

The import volume of the notified chemical will be disposed of primarily to landfill and through waste produced by recycling processes. A large majority of the notified chemical will be disposed of as normal office waste, ending up either in landfill or in paper recycling processes. The residual inks remaining in “empty” cartridges accounts for the remainder of notified chemical (5%). While some of this will be recycled, the majority will be disposed of to landfill.

5.6. Public exposure

Under normal usage, public exposure to the notified chemical will be negligible, because it is a minor component of the printer ink (0.5-7%), and because it is contained within the cartridges. Generally speaking, public exposure represents a smaller likelihood of exposure than workers. This is because the main public users would be owners of home printers.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Orange powder (the imported ink is a yellow liquid)

Melting Point/Freezing Point >352°C

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 Test was performed using Differential Scanning Calorimetry. However, the notified chemical decomposed from 352°C, forming black ash in a manner that required atmospheric oxygen. Therefore, no melting point could be determined.

TEST FACILITY Safepharm Laboratories (2004*a*)

Density 1597 kg/m^3 at 20.5 ± 0.5°C

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 Density was determined using a gas comparison pycnometer

TEST FACILITY Safepharm Laboratories (2004*a*)

Vapour Pressure <1.5 x 10^{-8} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
USA, EPA OPPTS Method 830.7950: Vapour Pressure.

Remarks Method: Vapour Pressure Balance.

Readings at lower temperatures were too low and variable for an appropriate statistical analysis. Instead, higher temperatures were analysed by regression, and a value for 25°C was extrapolated from the slope. A sequence of runs were started after a sample of test material had been under vacuum for 5¼ h. Temperature and pressure readings were taken between 190 and 250°C with a one hour dwell at 240°C between runs. The test material did not change in appearance under the conditions used in the determination.

The test substance is classified as very slightly volatile (Mensink *et al.* 1995).

TEST FACILITY Safepharm Laboratories (2004*b*)

Water Solubility 29.8-32.0% w/w of solution at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
USA, EPA OPPTS Method 830.7940: Water solubility: Column elution method; shake flask method.

Remarks Flask Method – Method variation: Due to high indeterminable saturation levels, it was not possible to prepare samples at five times the saturation level as recommended in the guidelines. Samples were prepared at different loading rates to ensure that the result is a true reflection of water solubility.

A 32% (w/w) solution had some visible insoluble material present; a 29.8% (w/w) solution did not. The pH of a saturated solution of the notified chemical was measured to have a pH value of ~7.5.

TEST FACILITY Safepharm Laboratories (2004*a*)

Surface Tension 72.6 ± 0.5 mN/m at 21.5°C

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

Remarks A 1.03 g/L solution of the notified chemical was used, with an interfacial tension balance.

The result was not corrected using the Harkins-Jordan correction table, as the correction was not applicable to the apparatus used. This change was not considered to have affected the integrity of the study.

The notified substance is not surface active.

TEST FACILITY Safepharm Laboratories (2004*a*)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
USA, EPA OPPTS Method 835.2110: Hydrolysis as a function of pH

pH	*T (°C)*	*t½*
4	25	> 1 year
7	25	> 1 year
9	25	> 1 year

Remarks After 120 hours (5 days) over the pH range and at 50ºC it was found that less than 10% of the test substance had hydrolysed, thus indicating a half-life of greater than 1 year at 25°C.

The notified chemical is not likely to hydrolyse in the environment.

TEST FACILITY Safepharm Laboratories (2004*a*)

Partition Coefficient (n-octanol/water) $\log_{10} P_{ow}$ = -3.44 at 20°C

METHOD OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.
USA, EPA OPPTS Method 830.7550: Partition Coefficient (n-octanol/water): Shake Flask Method.

Remarks Flask Method: the concentration in the aqueous phase was determined by HPLC, and that in the organic phase by spectrophotometry. The test was performed at neutral pH, as is appropriate for salts like the notified chemical.

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

TEST FACILITY Safepharm Laboratories (2004*a*)

Adsorption/Desorption $\log_{10}K_{oc} < 1.25$
– screening test

METHOD OECD TG 121 Estimation of the Adsorption coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
EC Directive 2001/59/EC C.19 Estimation of the Adsorption coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks Column temperature was 40°C. The mobile phase was pH 7.0, so the test reflects the ionised substance.

The HPLC screening method was used with 12 reference standards with known adsorption coefficients. The retention time of the test substance was 1.63 minutes which was less than that for acetanilide (4.001 minutes) which has a known log K_{oc} of 1.25, therefore the log adsorption coefficient is less than 1.25.

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

TEST FACILITY Safepharm Laboratories (2004*a*)

Dissociation Constant pKa values are predicted to range between –2.07 and –0.32.

METHOD A computer prediction of the pKa values was determined by the I-Lab Web Service v8.02.

Remarks This test was omitted, as the standard test methods are not applicable to substances with multiple pK_a values. The notified chemical contains multiple functional groups with a variety of pKa values. 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)	*Fraction*	*Mass (%)*
< 100	inhalable	21.9
< 10	respirable	4.11

Remarks Test was performed using a 100 μm sieve and a cascade impactor for the smaller particle sizes. Too few particles were < 10 μm to allow accurate assessment of mass median aerodynamic diameter (MMAD).

TEST FACILITY Safepharm Laboratories (2004*a*)

Flammability Limits Not highly flammable.

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

Remarks The notified chemical failed to ignite during the screening test, so the main test was not performed.

TEST FACILITY Safepharm Laboratories (2004*c*)

Autoignition Temperature >400°C

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

Remarks The notified chemical did self-ignite, but only after the oven temperature had reached 400°C.

TEST FACILITY Safepharm Laboratories (2004*b*)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
USA, EPA OPPTS Method 830.6316: Explodability

Remarks Not explosive on heating, friction or impact.

TEST FACILITY Safepharm Laboratories (2004*b*)

Oxidising Properties Not oxidising

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

Remarks Predicted not to be oxidising on the basis of chemical structure.

Reactivity Not expected to be reactive under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Female rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2421 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse Local Lymph Node Assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration test (CHL cells)	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical (82.6% pure)

METHOD:
- Species/Strain: Female Rat/Sprague Dawley CD Strain
- Vehicle: Dimethylsulfoxide (10mL/kg)
- Remarks - Method: Dosage was adjusted to correspond to the relatively low purity of the test substance (82.6%). Therefore, animals were dosed at higher levels to account for the lower quantity of notified chemical in the test substance. The dose recorded below describes the content of notified chemical (2000 mg/kg bw) in the administered dose (2421 mg/kg bw). The dose was administered by oral gavage.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 females	2000	None
2	3 females	2000	None

- LD50: >2000 mg/kg bw
- Signs of Toxicity: No signs of systemic toxicity were observed. All animals showed the expected gains in bodyweight over the study period.
- Effects in Organs: No gross abnormalities were detected.

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

TEST FACILITY: Safepharm Laboratories (2004*d*)

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical (82.6% pure)

METHOD: OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
- Species/Strain: Rat/Sprague-Dawley CD strain
- Vehicle: Arachis oil BP was used to make the notified chemical into a paste.
- Type of dressing: Semi-occlusive.
- Remarks - Method: Dosage was adjusted to correspond to the relatively low purity of the test substance (82.6%). Therefore, animals were dosed at higher levels to account for the lower quantity of notified chemical in the test substance. The dose recorded below describes the content of notified chemical (2000 mg/kg bw) in the administered dose (2421 mg/kg bw). The dose was administered to an area of skin (10% total body surface area), that had

been previously clipped of hair, and covered with a semi-occlusive dressing for 24 hours.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	No signs of dermal irritation were observed.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed, and all animals showed the expected gains in bodyweight over the study period.
Effects in Organs	No abnormalities were observed at necropsy.

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

TEST FACILITY Safepharm Laboratories (2004*f*)

7.3. Acute toxicity – inhalation

No test for inhalation toxicity was performed. The dermal route was considered the more likely route of exposure for the notified chemical, and hence this was chosen for the second acute toxicity study.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical (82.6% pure)

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	Three males
Vehicle	0.5 g notified chemical moistened with 0.5 mL water.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	4 hours of exposure to intact skin only. Animals were observed at 1, 24, 48 and 72 hours after exposure for evidence of primary irritation. An additional observation was made at 7 days to assess the reversibility of skin reactions.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema	1	0.33	1	1	7 days	0
Oedema	0	0	0	0	N/A	N/A

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

Remarks - Results Slight orange-coloured staining was observed at all treated skin sites at 1 hour and 24 hours after exposure, but this did not affect observations. All signs of erythema (slight) were fully reversible by seven days.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Safepharm Laboratories (2004*e*)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical (82.6% pure)

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	Three males
Observation Period	7 days
Remarks - Method	75 mg of dry notified chemical was placed into the conjunctival sac of the right eye only. An immediate pain assessment was performed, and then animals were observed at 1, 24, 48 and 72 hours after exposure for evidence of irritation. An additional observation was made at 7 days to assess the reversibility of any irritation.

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	1.7	1	0.33	2	7 days	0
Conjunctiva: chemosis	0.7	0.7	0.3	2	< 3 days	0
Conjunctiva: discharge	0.7	1	0.3	2	< 3 days	0
Corneal opacity	0	0	0	0	N/A	N/A
Iridial inflammation	0	0	0	0	N/A	N/A

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

Remarks – Results

Initially, a single rabbit was used, but based on the results two more were examined. All effects were fully reversible within 7 days.

Administration of the notified chemical to the rabbit's eyes caused slight initial pain reactions in all animals.

Orange coloured staining of the fur around all treated eyes was observed throughout the study. Yellow coloured staining of the nictitating membrane was also observed, persisting until after 72 hours.

CONCLUSION The notified chemical is slightly irritating to the eye

TEST FACILITY Safepharm Laboratories (2004*g*)

7.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical (96.5% pure)

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 OPPTS Method 870.3050 Repeated 28-day oral toxicity study in rodents

Species/Strain	Rat/Sprague-Dawley Crl:CD® (SD) IGS BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days for two recovery groups.
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

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

Control	5/sex	0	0
Control recovery	5/sex	0	0
Low dose	5/sex	25	0
Intermediate dose I	5/sex	150	0
Intermediate dose II	5/sex	300	0
High dose	5/sex	1000	0
High dose recovery	5/sex	1000	0

Mortality and Time to Death

No unscheduled deaths occurred during the study.

Clinical Observations

No clinically observable signs of toxicity were observed that could be related to treatment. Food/water consumption and functional performance tests in the treated groups were all comparable with control groups.

Red/brown coloured faeces and bright yellow urine were observed from all animals treated with 1000 mg/kg bw/day throughout the treatment period. This was associated with oral administration and subsequent excretion of a coloured substance, and not indicative of toxicity.

A statistically significant reduction in body weight gain in the high dose recovery male group was considered to be unrelated to treatment, as no reduction in body weight was observed in the high dose group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No treatment-related, statistically significant effects were observed.

A statistically significant reduction in platelet count in the high dose recovery male group was considered to be unrelated to treatment, as no reduction was observed in the high dose group. Similarly, some statistically significant changes in blood chemistry results in both males and females of the high dose recovery group were not observed in the high dose group, and were therefore thought to be of no toxicological importance.

Effects in Organs

No treatment-related effects in organ weight, macroscopic or microscopic abnormalities were detected.

Several statistically significant changes in organ weights were observed in various groups, but as similar results were not observed in the high dose group these were not deemed to be of toxicological importance. In the high dose recovery group, males were found to have reduced brain, liver and kidney weights, and females had increased adrenal gland weight.

Remarks – Results

While several statistically significant effects were observed in both males and females of the high dose recovery group, these were not considered to be toxicologically relevant, due to the absence of similar effects in the 28-day high dose group. Therefore, these results were not considered in the determination of the NOEL, which was based on the absence of toxicologically significant effects in the measured parameters at any dose in the study.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1000 mg/kg bw/day in this study, based on the lack of toxicologically significant effects in the parameters measured.

From these test results, the notified chemical was therefore not classified as harmful.

TEST FACILITY Safepharm Laboratories (2004*l*)

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

TEST SUBSTANCE	Notified chemical (82.6% pure)
METHOD	OECD TG 429 Skin Sensitisation – Local Lymph Node Assay
Species/Strain	Mouse, CBA/Ca strain, female
Vehicle	dimethylformamide
Number of Animals	Test Group: 3 x 4 animals; Control Group: 1 x 4 animals
Remarks - Method	25 µl of test solution (2.5%, 5.0% or 10% w/w in vehicle) was administered to the dorsal surface of each ear for three consecutive days. Dimethyl formamide was chosen as a vehicle because it allowed an appropriate concentration to be applied during the assay. Five days after topical application of the test material, the mice were injected into the tail vein with 20 µCi of 3H- methyl thymidine. Five hours later, the mice were killed by CO2 asphyxiation, and the lymph nodes excised and pooled for each experimental group. The radioactivity per lymph node was determined.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index* (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	670.92	N/A
2.5%	316.50	0.47
5.0%	588.67	0.88
10.0%	593.79	0.89
Positive Control α-hexylcinnamaldehyde		
5%	Not supplied	1.76
10%	Not supplied	2.78
25%	Not supplied	5.06

* A Stimulation Index of >3.0 indicates a positive result

Remarks - Results	No deaths or any signs of systemic toxicity were observed. Red/brown staining of the ears was observed in all animals treated with 5% or 10%.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Safepharm Laboratories (2004*h*)

7.9. Genotoxicity – bacteria

Note: The Ames test was performed three times. Initially, an impure sample (C-FG) of the notified chemical led to an aberrant positive result (Safepharm Laboratories (2004*i*)). Further analysis of this sample discovered that the genotoxic component arose from a minor impurity (Canon (2004*c*)). Further studies with a purified sample (C-FG-P) were found to be negative. Presented here are the results for C-FG-P (Safepharm Laboratories (2004*j*)).

TEST SUBSTANCE	Notified chemical (96.5% pure).
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 S9 rat liver microsomes
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate

Vehicle	Distilled water
Remarks - Method	A preliminary test was performed to determine the toxicity of the notified chemical.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	5000 (TA1535)		>5000	Negative
Test 2		>5000	>5000	Negative
Present				
Test 1	5000 (TA1535)		>5000	Negative
Test 2		5000 (TA1537)	>5000	Negative

Remarks - Results	A yellow colour was noted staining the plates from 50 µg/plate, but this did not affect the scoring of the plates. The test chemical caused no visible reduction in the bacterial background lawn at any dose level. No significant increases in revertants were observed for the test chemical. Positive controls verified both the assay and the S9 activation.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Canon (2004*a*), Canon (2004*c*), Safepharm Laboratories (2004*i*), Safepharm Laboratories (2004*j*)

7.10. Genotoxicity – in vitro (1)

Note: Two *in vitro* chromosome aberration tests in Chinese Hamster Lung cells were performed. Both indicated that the notified chemical was negative for genotoxicity. The second test is presented below.

TEST SUBSTANCE	Notified chemical (96.5% pure)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese Hamster Lung (CHL or CHL/IU) cells
Metabolic Activation System	Induced S9 rat liver microsomes
Vehicle	Cell culture medium
Remarks - Method	The concentrations of the notified chemical used in the preliminary cell growth inhibition test were 19.54-5000 µg/mL. No precipitation was observed, so the maximum concentration was used in the main tests. S9 were used at 5% final concentration in Test 1, and at 2% in Test 2. Two replicate samples were performed for each data point.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 125, 250, 500, 1000*, 2000*, 4000*	6 hours	24
Test 2	0*, 39.07*, 78.13*, 156.25*, 234.38, 312.5, 625	24 hours	24
Present			
Test 1	0*, 125, 250, 500, 1000*, 2000*, 4000*	6 hours	24
Test 2	0*, 312.5, 625, 1250*, 2500*, 3750, 5000*	6 hours	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	>4000 μg/mL		>4000 μg/mL	Negative
Test 2		≥156.25 μg/mL	>625 μg/mL	Negative
Present				
Test 1	>4000 μg/mL		>4000 μg/mL	Negative
Test 2		≥1250 μg/mL*	>5000 μg/mL	Negative

Remarks - Results

* Dose related increases in mitotic index were observed in the with-S9 exposure group at doses above 1250 μg/mL. These were considered to be due to toxicity-induced cell-cycle synchronisation.

Positive control samples were included in each experiment. All of these yielded their appropriate genotoxic responses, indicating that both the system and the S9 microsomes were performing appropriately.

CONCLUSION

The notified chemical was not clastogenic to CHL cells treated *in vitro* under the conditions of the test.

TEST FACILITY

Safepharm Laboratories (2004*k*)

7.11. Genotoxicity – in vitro (2)

TEST SUBSTANCE

Notified Chemical (~100% pure)

METHOD

Japanese test method (equivalent to OECD TG 473 In vitro Mammalian Chromosome Aberration Test).

Cell Type/Cell Line

Chinese Hamster Lung (CHL) cells

Metabolic Activation System

phenobarbital/5,6-benzoflavone-induced S9 rat liver microsomes

Vehicle

Sterile physiological saline

Remarks - Method

The concentrations of the notified chemical used in the preliminary cell growth inhibition test were 39-5000 μg/mL.

S9 were used at 5% final concentration.

Two replicate samples were performed for each data point.

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

Remarks - Results

Positive control samples were included in each experiment. All of these yielded their appropriate genotoxic responses, indicating that both the system and the S9 microsomes were performing appropriately.

CONCLUSION

The notified chemical was not clastogenic to CHL cells treated *in vitro* under the conditions of the test.

TEST FACILITY

Canon (2004*b*)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified substance

METHOD: OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Method of testing the biodegradability of chemical substances by micro-organisms, 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:
Analytical Monitoring: BOD by Closed system oxygen consumption measurement – soda lime.
TOC/DOC
HPLC
Remarks - Method: Reference substance – aniline
Concentration of suspended solids – 30 mg/L
Treatments:
- water + test substance – 100 mg/L – vessel 1
- sludge + test substance – 100 mg/L – vessel 2, 3 and 4
- sludge + aniline – 100 mg/L – vessel 6
- control blank – activated sludge only – vessel 5

The temperature was measured daily (25°C). BOD was measured by data sampler and autorecorder. At termination of study the dissolved organic carbon, test substance concentration and pH were measured.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	1	7	69
14	1	14	75
21	2	21	76
28	3	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	4	3	3	3
TOC	5	5	5	5
HPLC	2	0	1	1

Remarks - Results: All test validation criteria were met. The reference substance (aniline) degraded by 76% after 28 d confirming the suitability of the inoculum and test conditions.

CONCLUSION: Under the study conditions the test substance was not readily biodegradable.

TEST FACILITY: Kurume Laboratory (2004a)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 305C Bioconcentration: Flow-through Fish Test. EC Directive 98/73/EC C.13 Bioconcentration: Flow-Through Fish Test. Method of testing the degree of accumulation of chemical substances in fish bodies, in Testing methods for new chemicals substances, July 13 1974 (Revised October 8 1998), No 5 Planning and Coordination Bureau, Environment Agency.
Species	Carp (*Cyprinus carpio*)
Exposure Period	Exposure: 28 days
Concentration Range (Nominal)	1.0 mg/L (Level 1) 0.1 mg/L (Level 2)
Analytical Monitoring	HPLC
Remarks - Method	Continuous flow system. Test solutions were analysed once a week for a total of 8 times. Treated fish were analysed after 2, 4, 6 and 8 weeks of exposure (2 fish/analysis). There appears to have been no depuration phase. No abnormality in behaviour or appearance of the test fish was noted.
RESULTS	
Bioconcentration Factor	Level 1: 1.1 Level 2: ≤3.3
CONCLUSION	The results indicate that the notified chemical is not likely to bioaccumulate.
TEST FACILITY	Kurume Laboratory (2004b)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish (Rainbow trout)

TEST SUBSTANCE	Notified substance
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. 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 14°C, exposed to a photoperiod of 16 dark/8 hours light and were 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	93%*	20	0	0	0	0	0

*mean measurement of two analyses of freshly prepared solutions.

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 stayed within acceptable ranges.
CONCLUSION	Under the study conditions the test substance is very slightly toxic to fish (Mensink *et al.* 1995).
TEST FACILITY	SafePharm Laboratories (2004m)

8.2.1. Acute toxicity to fish (Orange-red killifish)

TEST SUBSTANCE	Notified Chemical
METHOD	Japanese Industrial Standard (JIS K 0102-1998-71.), "Testing Methods for industrial waste water, Acute toxicity test with fish".
Species	Orange–red killifish (*Oryzias laptipes*)
Exposure Period	96 h
Auxiliary Solvent	None
Remarks – Method	Water quality parameters of pH, water temperature, and O_2 content remained within normal limits throughout the study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0
250		10	0	0	0	0
500		10	0	0	0	1
1000		10	0	1	4	5

LC50	1000 mg/L at 96 hours.
NOEC	250 mg/L at 96 hours.
Remarks – Results	This was preliminary to the bioaccumulation test.
CONCLUSION	Under the study conditions the test substance is very slightly toxic to fish (Mensink *et al.* 1995).
TEST FACILITY	Kurume Laboratory (2004b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Substance
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	Based on range-finding tests it was determined that a limit test at 100 mg/L would be done. The concentration and stability were verified by analysis at 0 and 48 hours. The solutions were clear throughout the study. The test vessels (4 replicates), each with 10 daphnia, were covered, maintained at 21ºC, exposed to a photoperiod of 16 dark/8 hours light 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. Two controls were done in parallel.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
100	98%*	40	0	0

*mean measurement of two analyses of freshly prepared solutions.

LC50	>100 mg/L nominal at 48 hours
NOEC	100 mg/L nominal at 48 hours
Remarks - Results	No sublethal effects were observed in the daphnia throughout the study. All environmental parameters stayed within acceptable ranges.

CONCLUSION	Under the study conditions the test substance is very slightly toxic to aquatic invertebrates (Mensink *et al*. 1995).
TEST FACILITY	SafePharm Laboratories (2004n)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified substance
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: 3.2, 10, 32, 100 and 320 mg/L Actual: 3.06, 10.1, 32, 101 and 321 mg/L at time 0 hours Actual: 3.06, 10.2, 32.6, 104 and 330 mg/L at time 72 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Spectrophotometry
Remarks - Method	Two experimental methods were conducted in parallel to differentiate if the growth effects were due to toxicity or light intensity. Both used the same test concentrations and a cell density of $1.0 - 1.4 \times 10^4$ cells/mL. Constant illumination and stirring, and temperature maintained at 24 ± 1°C. Experiment A: 3 replicates per concentration and 3 controls. 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. The test solutions increased in yellow colour to bright orange intensity with increasing concentration. Experiment B: 3 replicates per concentration and 3 controls. 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.

Test solutions from experiment A at 0 and 72 hours were analysed to confirm concentration. It was found that the test concentrations ranged from 96 to 104% of the nominal concentration. Hence, nominal concentrations were used in analysis.

RESULTS

Experiment A: Growth			*Experiment B: Growth*		
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*NOEC mg/L*	*E_bC50 mg/L at 72 h*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
110	>320	3.2	34	>320	3.2

Remarks - Results

In experiment A, both the growth and biomass were affected by the presence of the test substance.

In experiment B, both the growth and biomass were affected by the reduction in light due to the presence of the test substance in the Petri dish.

In both experiments the cell concentration in the controls increased by a factor greater than 16 after 72 hours, which meets the validity criteria.

Since the inhibition of growth was similar in both Experiment A and Experiment B the growth inhibition is attributable to the reduction of light intensity due to the highly coloured nature of the test material rather than intrinsic toxic properties of the test material.

CONCLUSION

Under the study conditions, the test substance is very slightly toxic to algae (Mensink *et al.* 1995)

TEST FACILITY

SafePharm Laboratories (2004o)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified Substance

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

Reference substance – 3,5-dichlorophenol.

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} = 12 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 test substance is not toxic to micro-organisms.
TEST FACILITY	SafePharm Laboratories (2004p)

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 during use 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 salts.

Emptied ink cartridges containing a residue of notified chemical may be recycled or be sent to landfill for disposal. During recycling the cartridges will be dismantled and the notified chemical will be washed off, ultimately finding its way into onsite treatment works prior to discharge into the sewer. As a worst case, this would account for 50 kg of the notified chemical being discharged to sewer, assuming all cartridges were recycled and no removal occurs in onsite treatment works. In a landfill, the notified chemical is expected to be immobile, and eventually it will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

Approximately 50% of the printed paper will enter the recycling process. During the recycling process, waste 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 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). Based on the releases to sewer from the recycling of cartridges and printed paper. The predicted environmental concentration (PEC) of the notified chemical would be:

Amount in effluent entering sewer	900 kg
Number of days	365
National population	20.1 million
Litres per person	200 L
PEC_{sewer}	0.60 µg/L.

A bioaccumulation study with carp found bioconcentration factors between ≤3.0 times indicating that the chemical is not likely to bioaccumulate.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified chemical is harmful to algae, very slightly toxic to fish and daphnia and not toxic to microorganisms. The most sensitive species are algae, where the E_bC50 of 34 mg/L. Acute results are available for 3 trophic levels, so it is applicable to apply an assessment factor of 100 to the most sensitive species (algae), thus the predicted no effect concentration (PNEC) is 340 µg/L.

9.1.3. Environment – risk characterisation

A worst-case calculation indicates a PEC/PNEC ratio of >>0.01 (0.60/340) for aquatic ecosystems via sewer discharge, indicating a low environmental risk.

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

Importation/Dockside/Storage and transport workers

As the notified chemical will be imported in pre-packed, sealed cartridges, workers are unlikely to be exposed to the notified chemical except in the unlikely event of accidental rupture during transport and storage.

Office worker /Service technician

Workers may be exposed to the notified chemical through dermal contact while changing spent cartridges, repairing printers or during normal printing processes. Due to the notified chemical being contained within sealed cartridges, dermal exposure would only occur occasionally and in minute quantities. In addition, workers would avoid exposure with wet inks because it would stain the skin and/or smudge an undried printed page. Some intermittent exposure may occur when printing onto non-absorbent media when the ink has not yet dried. After drying, exposure to the notified chemical on paper printed with ink containing the notified chemical is low as the dye is bound to the paper matrix.

Service technicians are expected to have the highest occupational exposure, but this will be minimised by their use of disposable gloves.

In the unlikely situation where the entire palms of a worker's hands are covered with ink containing a maximum of 7% notified chemical, exposure could be estimated as follows:

Product	*Concentration of notified chemical in product (mg/cm^3)[a]*	*Contact Area (cm^2)[b]*	*Thickness of Product Layer on Skin (cm)[b]*	*Dermal Absorption (%)[b]*	*Frequency of occurrence (per day)[c]*	*Exposure to notified chemical (mg/kg bw/day)[d]*
Ink	70	420	0.01	10	1	0.42

[a] assuming ink has a specific gravity of 1.
[b] data from European Chemical Bureau Technical Guidance Document on Risk Assessment (European Commission, 2003).
[c] no frequency data is available. The occurrence of this scenario once per day is considered to be reasonable worst-case.
[d] assuming 70kg body weight

Ocular, oral and inhalation exposure are not expected to occur during normal use.

9.2.2. Public health – exposure assessment

As consumers, the public may be intermittently exposed to the notified chemical in a similar fashion to office workers – when replacing spent cartridges and from undried printed media. However, the consumers are less likely to use the printer as often as workers, and therefore their potential exposure is expected to be lower. Accidental dermal exposure to ink containing the notified chemical would also be avoided because of skin staining and/or smudging of undried printed media.

Ocular, oral and inhalation exposure are not expected to occur during normal use.

Overall, exposure of the public is expected to be low, due to the small quantity of notified chemical in each cartridge, the sealed design of cartridges, the automated release during printing, and intermittent nature of exposure.

9.2.3. Human health – effects assessment

Toxicokinetics, metabolism and distribution

In the Repeated Dose 28-day Oral Toxicity Study in rats, urine and faeces were observed to coloured, indicating that the notified chemical and/or its coloured metabolites are excreted via these routes. Additionally, colouration of urine indicates that the notified chemical is absorbed

from the gastrointestinal tract.

Absorption of the notified chemical through the skin is expected to be very low, due to the high molecular weight of the notified chemical and its low log Pow. This is supported by the lack of acute dermal toxicity observed.

Acute toxicity
The notified chemical is considered to be of low acute toxicity when administered orally or when applied to the skin. Inhalation toxicity has not been determined, however, exposure to the notified chemical through inhalation is unlikely.

Irritation and Sensitisation
Rabbit studies of eye and skin irritation found that the notified chemical is slightly irritating to both skin and eyes. The notified chemical caused staining of the skin for up to 24 hours, and erythema persisted up to 3 days. The notified chemical also caused staining of the nictitating membrane of the eye, which also persisted for up to 3 days. All effects were fully reversible by 7 days after exposure.

The notified chemical is not considered to be a sensitiser, based on the mouse local lymph node assay results.

Repeated Dose Toxicity
The 28-day repeat dose oral toxicity study in rats showed that the notified chemical did not cause any adverse reactions that could be associated with its administration. Based on this, a No Observable Effect Level (NOEL) was established as 1000 mg/kg bw/day. It is therefore considered to be of low toxicity.

Mutagenicity
The notified chemical was found to be non-mutagenic in two independent Ames tests and non-clastogenic in two independent *in vitro* chromosomal aberration tests in cultured CHL cells. It is therefore not considered to be genotoxic in vitro.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a minor component of printer inks (0.5-7%). Dermal exposure to ink is unlikely when cartridges are handled carefully, and it should only occur sporadically. In the event of dermal exposure, toxicity is unlikely as any potential exposure is expected to occur in only small quantities, and because the notified chemical is not classified as hazardous. If the likelihood of exposure to ink in greater quantities or with greater frequency is likely, then the appropriate PPE should be worn to reduce any potential risk (eg, gloves for inkjet printer service technicians). Ocular, oral or inhalation exposure to the notified chemical should not occur during normal use.

9.2.5. Public health – risk characterisation

The notified chemical is a minor component of printer inks (0.5-7%). Dermal exposure to ink is unlikely when cartridges are handled carefully, and it should only occur sporadically. In the event of dermal exposure, toxicity is unlikely as any potential exposure is expected to occur in only small quantities, and because the notified chemical is relatively non-toxic. Ocular, oral or inhalation exposure to the notified chemical should not occur during normal use.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes. On environmental grounds the notified substance would have the classification of Chronic 3.

Based on the available data, the notified chemical does not meet the criteria for the Classification and Labelling of Chemicals according to the United Nations (2003) Globally Harmonised System.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when the notified chemical is used as a component of pre-packed inkjet printer inks.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was were 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 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

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 routine maintenance and repairs.

- 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.

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 soaking up spilled ink with absorbent material.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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