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September 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C-BG

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT (S)
Canon Australia Pty Ltd (ABN 66 005 02 951)
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 Identity
Spectral data
Purity and identity of impurities

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

Dissociation constant
Flash point
Acute inhalation toxicity
Genotoxicity – in vivo
Acute/chronic toxicity to aquatic invertebrates
Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT (S)
LVC/657

NOTIFICATION IN OTHER COUNTRIES
UK (VIIC in 2004, VIIA in 2005)
USA (2004)
Canada, Ontario state (2004)
Japan (2004)
Philippines (Small Quantity Importation Clearance in 2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME (S)
C-BG (preferred marketing name)
JPD BLACK C-BG
JPD BLACK C-BG Liquid
Substituted naphthalene sulfonic acid

METHODS OF DETECTION AND DETERMINATION

METHOD	High Performance Liquid Chromatography (HPLC), Infrared (IR) Spectroscopy, ^{1}H Nuclear Magnetic Resonance (NMR) Spectroscopy and Ultraviolet/Visible light (UV/Vis) Spectroscopy
Remarks	HPLC using UV/Vis detection allows the quantification of the notified chemical. The identity was confirmed by, ^{1}H NMR, UV/Vis and IR Spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
> 75 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of ink in sealed ink-jet printer cartridges at a concentration of 0.5 % to 7 %.

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 acts as a dyestuff in printing ink.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

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

TRANSPORTATION AND PACKAGING
The size of the imported ink cartridge is 12 mm x 20 mm x 15 mm – 70 mm x 30mm x 120mm. Each cartridge contains 2–150 mL of ink. Transport in Australia will be by road; no special transport requirements are necessary.

5.2. Operation description

No processing such as reformulation, repackaging, filling or refilling of the cartridges containing the notified chemical, or any other handling of the notified chemical is carried out in Australia. Sealed ink cartridges containing the notified chemical will be handled by service technicians, office workers or the public, who will replace spent cartridges in the printers as necessary. Office workers and the public will use the printers for varied printing work.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Importation/Waterside	50	< 8 hours/day	10-50 days/year
Storage and Transport	15	< 8 hours/day	10-50 days/year
Office worker/consumer	2,000,000	10 seconds /day	2 days/year
Service Technicians	100	1 hour/day	170 days/year

Exposure Details
Waterside, storage and transport workers will only handle the sealed cartridges containing the notified chemical and therefore exposure is not expected unless the packaging is accidentally breached.

Service technicians may be exposed to the ink containing up to 7 % notified chemical during repair and cleaning of ink jet printers. Due to the low volatility of the notified chemical, dermal exposure is expected to be the main potential route of exposure. Exposure to the notified chemical may occur while changing cartridges if the ink is inadvertently handled.

Instructions on how to replace the cartridge safely are included with the cartridge. During the printing process, the ink turns into an extremely fine mist and is transferred to the paper. However, mist emission of the non-volatile components of the ink from the printer is expected to be low. Occasional dermal exposure during use of the printer may occur if the printed pages were handled inadvertently before the ink had dried, or if ink-stained parts of the printer were touched. Once the ink dries, the chemical would be bonded to the printed-paper, and therefore dermal exposure to the notified chemical from contact with the dried ink is not expected. Dermal exposure is also possible if non-absorbent substrates are inadvertently used for printing.

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. However if there was 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
The office staff and general public will change the cartridges. Release of the ink solution to the environment is not expected under normal use as 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.

Ultimately, the majority of the notified substance suffers 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 that will be recycled or be disposed of to landfill. Cartridges are processed to recycle their component materials into new products. During the recycling process the residual ink will be washed from the cartridges and washings discharged to onsite wastewater treatment plants before release to sewer.

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 substance annually.

5.6. Public exposure
The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers (see section 5.3 above). However, it is expected that the public will be printing less often than office workers.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Black powder

Melting Point Unable to be determined, decomposes from 221ºC

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 Determined by differential scanning calorimetry. The test material was found to decompose from 221ºC at 98.23 kPa. As the test material decomposed, no value for melting temperature could be determined.

TEST FACILITY SafePharm Laboratories (2004a)

Density 1760 kg/m^3 at 20 $\pm$ 0.5ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.

Remarks Determined by gas comparison pycnometer.

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Vapour Pressure < 1.8 x 10^{-7} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks Determined by vapour pressure balance system with measurements being made at several temperatures and linear regression analysis used to calculate the maximum vapour pressure at 25ºC. A sequence of runs was started after a sample of test material had been under vacuum for 122 h. Temperature and pressure readings were taken between 236 and 246°C with a one hour dwell at 236°C between runs. The test substance is classified as slightly volatile (Mensink *et al.* 1995).

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004b)

Water Solubility 19.6 % (w/w) at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Determined by Flask Method. Analytical method: HPLC.
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.

The preliminary estimate of water solubility was 22.7 % (w/w). In the main study the concentration range was 19.3 % to 20.0 %. This result indicates that the notified substance would be very readily soluble in water (Mensink, 1995).

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Hydrolysis as a Function of pH

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

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

Remarks The nominal concentration of the test solutions was 2.0 g/L. Aliquots (in duplicate) of sample solutions were taken at various times (0, 2.4, 24 and 120 hours) and the pH of the solution was recorded.

After 120 hours (5 days) at all pHs 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.

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

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Partition Coefficient (n-octanol/water) log Pow < -4.71

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

Remarks Shake Flask Method
Six measured amounts of the test substance and water saturated n-octanol were shaken by inversion at 22.5-23.5ºC for 5 minutes. Aliquots of both the water and n-octanol phases were taken for analysis by HPLC.

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

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Adsorption/Desorption log K_{oc} <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 the use of 12 reference standards with known adsorption coefficients. The retention time of the test substance was 1.567 minutes, which was less than that for acetanilide (4.115 minutes), which has a known, log K_{oc} of 1.25; therefore the log adsorption coefficient is less than 1.25.

The test was done at pH 7 and therefore reflects the ionised substance.

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

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Dissociation Constant A range of pKa values calculated to be between –1.72 and 11.24

Remarks The notified chemical contains multiple functional groups with a variety of pKa values. The various pKa values provided by the notifier were calculated by I-Lab Web Service version 8.02. Eleven reference groups related to functional groups in the notified substance were entered into the model and the predicted pKa values obtained. The notified substance has strong acid functionalities, and will remain ionised throughout the environmental pH range of 4 to 9 as well as basic functionalities which are expected to display typical basicity.

Particle Size

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

Range (μm)	*Mass (%)*
< 100 (inhalable fraction)	20.0
< 10 (respirable fraction)	2.53

Remarks In a preliminary study the notified chemical was sieved for approximately 10 minutes using a 100 μm sieve. The main study was conducted using the cascade impactor method. Air containing the notified chemical enters the inlet port at a rate of 60 litres/minute. The impactor consists of five stages with cut-point aerodynamic diameters of 10, 5, 2.5, 1.25 and 0.625 μm, and a final glass fibre filter. Particles not deposited in the artificial throat are deposited according to size in collection cups.

Too few particles were of a size < 10 μm to allow accurate assessment of mass median aerodynamic diameter.

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004a)

Flash Point Not determined

Remarks

Flammability Limits Not highly flammable

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

Remarks In the preliminary test the notified chemical failed to ignite and therefore the substance can be considered not highly flammable. The moisture content was calculated to be 2.2 % (w/w).

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004g)

Autoignition Temperature > 400°C

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

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004b)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks The notified chemical was tested for thermal sensitivity, mechanical sensitivity with respect to shock and mechanical sensitivity with respect to friction.

Test conducted in accordance with GLP standards.

TEST FACILITY SafePharm Laboratories (2004b)

Reactivity

Remarks The notified chemical is stable under normal conditions of use. The chemical is hydrolytically stable but decomposes at temperatures above 221°C.

Surface Tension 72.4 mN/m at 19.0 ± 0.5°C

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Concentration: 1.02 g/L An interfacial tension balance was used to determine the surface tension. Test conducted in accordance with GLP standards.
TEST FACILITY	SafePharm Laboratories (2004a)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Assessment Conclusion*
Rat, acute oral, LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal, LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	not provided
Rabbit, skin irritation	mild irritant
Rabbit, eye irritation	mild irritant
Mouse, skin sensitisation – LLNA	non-sensitiser
Rat, repeat dose oral toxicity – 28 days.	NOEL 150 mg/kg bw/day
Genotoxicity – bacterial reverse mutation (two independent studies)	non-mutagenic
Genotoxicity – in vitro chromosome aberration test (two independent studies)	non-clastogenic
Genotoxicity – in vivo	not provided

7.1. Acute toxicity – oral

TEST SUBSTANCE	C-BG (85.7% purity)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Dimethylsulfoxide
Remarks - Method	No significant protocol deviations. A correction factor was applied to account for the purity of the test material. Test conducted in accordance with GLP standards.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 female	2334*	0
II	3 female	2334*	0

*equivalent to 2000 mg/kg bw notified chemical.

LD50	> 2000 mg/kg bw
Signs of Toxicity	Signs of systemic toxicity noted during the study were hunched posture, ataxia as well as eyes, ears, feet and tail black in colour. Animals appeared normal, four, five or ten days after dosing.
Effects in Organs	Black staining of the liver and/or kidneys was noted at necropsy
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2004h)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	C-BG (85.7% purity)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley.
Vehicle	Test substance moistened with distilled water.
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations. A correction factor was applied to account for the purity of the teat material. Test conducted in accordance with GLP standards.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 male	2334*	0
II	5 female	2334*	0

*equivalent to 2000 mg/kg bw notified chemical.

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight to well-defined erythema was noted at six treated skin sites up to four days after dosing. Physical damage, caused by attempted removal of adhered test material, crust formation and small superficial scattered scabs were also noted. Treated skins sites appeared normal two, six or seven days after dosing, except for four treated skin sites where no evidence of skin irritation was noted.
Signs of Toxicity - Systemic	There were no deaths or signs of systemic toxicity. All animals showed expected gains in bodyweight except for one female, which showed bodyweight loss during the first week and expected gain in bodyweight during the second week of the study.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	SafePharm Laboratories (2004i)

7.3. Acute toxicity – inhalation

Not provided. The notified chemical is a low volatility solid that is imported into Australia only as a component of a liquid preparation in sealed cartridges. Inhalation exposure is therefore considered to be an unlikely route of exposure.

7.4. Irritation – skin

TEST SUBSTANCE	C-BG (85.7% purity)
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	Test substance moistened with distilled water.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Test conducted in accordance with GLP standards.

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	0.33	0.33	1	1	72 hours	0
Oedema	0	0	0	0	N/A	0

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

Remarks - Results

Very slight black staining was noted in all three-treatment sites at the 1-hour observation and in two treatment sites after the 24-hour observation. This did not effect evaluation of skin reactions.

Very slight erythema was noted at all treated skin sites one hour after patch removal and at the 24-hour observation and persisted at one treated skin site at the 48 and 72-hour observations.

Two treated skin sites appeared normal at the 48-hour observation and the remaining treated skin site appeared normal at the 7-day observation.

CONCLUSION The notified chemical is mildly irritating to the skin.

TEST FACILITY SafePharm Laboratories (2004j)

7.5. Irritation – eye

TEST SUBSTANCE C-BG (85.7% purity)

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

Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 14 days
Remarks - Method No significant protocol deviations. Due to the ocular severity noted in the first treated animal, no additional animals were treated.

Test conducted in accordance with GLP standards.

RESULTS

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

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

Remarks - Results

Black staining of the fur was noted around all treated eyes throughout the study. Black staining of the conjunctival membranes and/or cornea was noted in all treated eyes during the study. One treated eye appeared normal at the 72-hour observation, one other treated eye appeared normal at the 7-day observation and the remaining treated eye appeared normal at the 14-day observation.

CONCLUSION	The notified chemical is classified as mildly irritating to the eye.
TEST FACILITY	SafePharm Laboratories (2004k)

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

TEST SUBSTANCE	C-BG (85.7% purity)
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/CBA Ca
Vehicle	Propylene glycol
Remarks - Method	Three groups, each of four animals were treated with 50 µL (25 µL per ear) of the test material at concentrations of 5 %, 10 % and 25 %. A further group of four animals was treated with propylene glycol alone. Test conducted in accordance with GLP standards.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	433.79	N/A
5	672.30	1.55
10	575.36	1.33
25	1022.76	2.36
Positive Control (α-hexylcinnamaldehyde)		
5	-	1.76
10	-	2.78
25	-	5.06

Remarks - Results	There were no deaths. No signs of systemic toxicity were noted in the test or control animals during the study. Black staining of the ears and fur was noted in all test animals one hour after dosing, on Days 1, 2 and 3.
CONCLUSION	The test substance was considered to be a non-sensitiser under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2004l)

7.7. Repeat dose toxicity – 28 day oral toxicity study in the rat

TEST SUBSTANCE	C-BG (85.7% purity)
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).
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. A correction factor was applied to account for the purity of the test material. Test conducted in accordance with GLP standards.

RESULTS

Group	*Number and Sex of Animals*	*Dose* mg/kg bw/day*	*Mortality*
I (control)	5 male, 5 female	0	0
II (low dose)	5 male, 5 female	25	0
III (mid dose 1)	5 male, 5 female	150	0
IV (mid dose 2)	5 male, 5 female	300	0
V (high dose)	5 male, 5 female	1000	0
VI (control recovery)	5 male, 5 female	0	0
VII (high dose recovery)	5 male, 5 female	1000	0

* dose level of notified chemical

Mortality and Time to Death

No mortality was observed during the study

Clinical Observations

No clinically observable signs of toxicity were detected.

Dark staining and/or faeces on the cage tray-liners was evident from Day-2 for Group IV and Group V animals of either sex, together with associated findings of blue stained fur in Group III animals of either sex from Day-12 onwards. From Day 19 Group V animals of either sex developed dark eyes. All findings were associated with oral administration and subsequent excretion of a coloured test material and were not indicative of toxicity.

All findings other than colouration were still evident in Group VI animals during the treatment free period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry

Group IV and Group V animals of either sex showed a statistically significant increase in plasma bilirubin when compared to controls ($p < 0.05$). The majority of the individual values were outside the respective reference ranges for rats of the strain and age used. Plasma bilirubin was also elevated for Group VI females following fourteen days without treatment.

No toxicologically important changes were detected at the other dose levels or in Group VI males following fourteen days without treatment.

Haematology

There were no treatment-related changes in the haematological parameters measured.

Urinalysis

Group III, Group IV and Group V animals of either sex showed dark coloured urine making assessment difficult. Urine colouration may be observed following oral administration of a coloured test material and is considered not to be indicative of toxicity. Urine colour was comparable with controls by the end of the study.

Effects in Organs

Organ Weights

There were no treatment-related changes in organ weights measured.

Gross Pathology

Discolouration was detected in the majority of tissues in Group V animals of either sex. Dark staining was also evident in the kidneys and the stomach of Group IV animals whilst dark kidneys were seen in animals of either sex in Group III. The discolouration was a consequence of oral administration of a coloured test material and did not represent an adverse effect.

Group VI animals continued to show dark kidneys following fourteen days without treatment, females showed dark ovaries and males showed dark testes.

No abnormalities were observed in Group II animals.

Histopathology

The following treatment related changes were detected:

Stomach: Agglomeration of gastric secretion, hyperplasia of mucous secreting cells and superficial mucosa; basophilia were observed in relation to treatment for animals of either sex in Group V. A higher incidence of agglomeration of secretion was also seen for females and also male animals in Group IV. Gastric changes had appreciably regressed by the end of the study.

Kidneys: Colouration due to the nature of the test material was observed but did not represent an adverse health effect.

Remarks – Results
Blood chemical investigations revealed a statistical increase ($p < 0.05$) in plasma bilirubin for animals of either sex treated with 1000 or 300 mg/kg/day. Many individuals were outside the respective reference range. Whilst this parameter is an indication of liver function, without any organ weight or histopathological correlation the increase is inconclusive. However, given the magnitude of the increase, early indication of possible target organ toxicity may have been identified at those levels.

CONCLUSION
Oral administration of C-BG to rats for a period of twenty-eight consecutive days at dose levels of up to 1000 mg/kg/day resulted in toxicologically significant effects at 1000 and 300 mg/kg/day. No such changes were demonstrated in animals treated with 150 or 25 mg/kg/day and the No Observed Effect Level (NOEL) was therefore considered to be 150 mg/kg bw/day.

TEST FACILITY SafePharm Laboratories (2004m)

7.8.1. Genotoxicity – bacteria

TEST SUBSTANCE C-BG (85.7% purity)

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*: WP2uvrA$^-$
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver.
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 correction factor was applied to account for the purity of the test material. Test conducted in accordance with GLP standards.

RESULTS

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

Remarks - Results No toxicity or precipitation was observed. A blue colour was observed at and above 150 µg/plate but this did not prevent the scoring if revertant colonies.

The test substance did not cause a marked increase in the number of revertants per plate of any of the bacterial strains either in the presence or absence of metabolic activation. The positive controls confirmed the activity of the activation system and the sensitivity of the test system.

CONCLUSION The notified chemical was considered to be non-mutagenic to bacteria under the conditions of the test.

TEST FACILITY SafePharm Laboratories (2004n)

7.8.2 Genotoxicity – bacteria

TEST SUBSTANCE C-BG (purity 100%)

METHOD The test was carried out according to "Standards for Mutagenicity Test using Microorganisms" of "Occupational Safety and Health Law".
Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA/pKM101
Metabolic Activation System	S9 fraction from phenobarbital and 5,6-benzoflavon induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 312.5 - 5000 µg/plate b) Without metabolic activation: 312.5 - 5000 µg/plate
Vehicle	Sterilised pure water
Remarks - Method	Two plates of each dose were used in the tests rather than three. Test conducted in accordance with GLP standards.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5000			
Test 1		> 5000	> 5000	negative
Test 2				
Present	> 5000			
Test 1		> 5000	>5000	negative
Test 2		> 625	> 625	negative

* >50% decrease in the mean number of revertant colonies

Remarks - Results	The test substance did not cause a marked increase in the number of revertants per plate of any of the bacterial strains either in the presence or absence of metabolic activation. The positive controls confirmed the activity of the activation system and the sensitivity of the test system.

CONCLUSION The notified chemical was determined to be non-mutagenic to bacteria under the conditions of the test.

TEST FACILITY Canon (2004a)

7.9.1 Genotoxicity – in vitro

TEST SUBSTANCE C-BG (purity 85.7%)

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.

Species/Cell Line	Chinese Hamster Lung cell

Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver.
Vehicle	Minimal Essential Media
Remarks - Method	No significant protocol deviations. A correction factor was applied to account for the purity of the test material in the main tests.
	Test conducted in accordance with GLP standards.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	0*, 19.53, 39.06, 78.13*, 156.25*, 234.38, 312.5*	24 hours	24 hours
Present			
Test 1	0*, 156.25, 312.5, 625, 1250*, 2500*, 5000*	6 hours	24 hours
Test 2	0*, 234.38, 312.5, 625, 1250*, 2500*, 5000*	6 hours	24 hours

*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	5000	> 5000	> 5000	negative
Test 2	312.5	234.8	>312.5	negative
Present				
Test 1	2500	2500	> 5000	negative
Test 2	2500	2500	> 5000	negative

Remarks - Results	The test material did not induce any statistically significant increases in the frequency of cells with structural or numerical chromosome aberrations following either 24 hours continuous exposure in the absence of activation or 6(18) hour pulse exposure in the presence or absence of activation. The test material did not induce any statistically significant increases in the number of polyploid cells at any dose level in either exposure group. The positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was non-clastogenic to Chinese Hamster Lung Cells treated in vitro under the conditions of the test.
TEST FACILITY	SafePharm Laboratories (2004o)

7.9.2 Genotoxicity – in vitro

TEST SUBSTANCE	C-BG (purity 100%)
METHOD	Chromosome Aberration Test – in house method
Species/Cell Line	Chinese hamster lung cells
Metabolic Activation System	S9 fraction from phenobarbital and 5,6-benzoflavon induced rat liver.
Vehicle	Sterile physiological saline
Remarks - Method	No significant protocol deviations.
	Test conducted in accordance with GLP standards.

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

Test 2	1250*, 2500*, 5000*	6 hour	24 hour
Test 3a	39, 78, 156, 313*, 625*, 1250*, 2500, 5000	24 hour	24 hour
Test 3b	39, 78, 156*, 313*, 625*, 1250, 2500, 5000	48 hour	48 hour
Test 4a	625*, 884*, 1250*, 1770	24 hour	24 hour
Test 4b	156*, 313*, 625*, 1250	48 hour	48 hour
Present			
Test 1	39, 78, 156, 313, 625, 1250*, 2500*, 5000*	6 hour	24 hour
Test 2	625, 1250*, 2500*, 5000*	6 hour	24 hour

*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	> 5000	> 5000	> 5000	negative
Test 2	> 5000	> 5000	> 5000	negative
Test 3a	1250	1250	> 5000	negative
Test 3b	1250	625	> 5000	negative
Test 4a	1250	1250	>1770	negative
Test 4b	1250	625	>1250	negative
Present				
Test 1	> 5000	> 5000	> 5000	negative
Test 2	> 5000	> 5000	> 5000	negative

Remarks - Results

The positive controls confirmed the sensitivity of the test system.

CONCLUSION

The notified chemical was non-clastogenic to Chinese Hamster Lung Cells treated in vitro under the conditions of the test.

TEST FACILITY Canon (2004b)

7.10. Genotoxicity – in vivo

Not provided.

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 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

Temperature 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.

Test conducted in accordance with GLP standards.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	46
14	0	14	76
21	0	21	78
28	0	28	79

Percentage biodegradation via different methods – ONLY in test solutions (Vessels 2, 3 & 4)

Method	% degradation			
	Vessel 2	Vessel 3	Vessel 4	Average
BOD	0	0	0	0
TOC	4	2	3	3
HPLC	1	0	0	0

Remarks - Results: All test validation criteria were met. The reference substance (aniline) degraded by 78.4% 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 305 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
Auxiliary Solvent:
Concentration Range:
Nominal: 2.0 mg/L (Level 1)
0.2 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.

Test conducted in accordance with GLP standards.

RESULTS

Bioconcentration Factor	Level 1	≤0.3
	Level 2	≤3.0

CONCLUSION The above 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

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/L $CaCO_3$
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 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 hours light/8 hours dark 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. Test conducted in accordance with GLP standards.

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	94-100%	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 stayed within acceptable ranges.

CONCLUSION Under the study conditions the test substance is non toxic to fish (Mensink *et al.* 1995).

TEST FACILITY SafePharm Laboratories (2004c)

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, O_2 content remained within normal limits throughout the study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*	
Nominal	*Actual*		*24 h*	*48 h*
Control		10	0	0
300		10	0	0

LC50	>855 mg/L at 96 hours.
NOEC	855 mg/L at 96 hours.
Remarks – Results	

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 chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction 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/L $CaCO_3$
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 21°C, 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. Two controls were done in parallel. Test conducted in accordance with GLP standards.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
100	98.5%	40	0	0

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 (2004d)

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 and 100 mg/L Actual: 0.992, 3.19, 9.78, 31.7 and 98.4 mg/L at time 0 hours Actual: 0.872, 3.08, 9.58, 31.1 and 96.8 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 1.16 $\times 10^4$ 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 pink colour to dark red 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 87 to 100% of the nominal concentration. Test conducted in accordance with GLP standards.

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*
2.0 (CI 1.5-2.6)	6.6	1.0	2.1 (CI 1.7-2.6)	4.9 (CI 3.4-7.1)	1.0

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 an intrinsic toxic properties of the test material.
CONCLUSION	Under the study conditions, the test substance is moderately toxic to algae (Mensink *et al.* 1995)
TEST FACILITY	SafePharm Laboratories (2004e)

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. Reference substance – 3,5-dichlorophenol Rate of respiration was determined after 30 minutes and 3 hours contact. Total water hardness – 100 mg/L $CaCO_3$. Test conducted in accordance with GLP standards.
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 microorganisms.
TEST FACILITY	SafePharm Laboratories (2004f)

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 of 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 2.0 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 20 μg/L.

9.1.3. Environment – risk characterisation

The worst-case calculation indicates a PEC/PNEC ratio of 0.03 (0.60/20) 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

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 may be exposed to the notified chemical through dermal contact while changing

spent cartridges or during normal printing processes. Service technicians may be exposed to the notified chemical through dermal contact while changing spent cartridges, repairing printers or during normal printing processes.

Ocular and inhalation exposure are not expected. Service technicians are expected to have the highest potential occupational exposure. However, for all workers, due to the design of the cartridge dermal exposure is likely to occur only occasionally and to small quantities of the notified chemical at a concentration of <7% and as such dermal exposure is expected to be low. In addition, exposure is to be avoided because it would stain the skin and/or smudge the printed page. Exposure will be minimised by the use of disposable gloves by service personnel.

Exposure to the notified chemical on printed-paper is low as the dye is bound to the paper matrix. Some intermittent exposure may occur if printing onto a non-absorbent substrate occurs and the ink does not dry for a time.

In the situation where a worker's entire palms of the hands are covered with the ink containing 7% notified chemical, exposure would 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

9.2.2. Public health – exposure assessment

Similarly to office workers, the public may be intermittently exposed to the notified chemical when replacing spent cartridges, and during use of printers, however, as it is expected that the public will be using the printer less often than workers, exposure is also expected to be lower. Dermal exposure to ink containing the notified chemical could occur accidentally but would be avoided because skin staining and/or smudging of the printed page. Exposure to the notified chemical is considered to be limited to the dermal route.

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

9.2.3. Human health – effects assessment

Repeated Dose Toxicity

In a 28-day repeat dose oral toxicity study in rats, the following treatment related findings were observed:

Animals dosed with 300 mg/kg bw/day exhibited a higher incidence of agglomeration of gastric secretion. Animals dosed with 1000 mg/kg bw/day exhibited agglomeration of gastric secretion, hyperplasia of mucous secreting cells and superficial mucosa and basophilia. Gastric changes had appreciably regressed by the end of the study.

Animals treated with 300 or 1000 mg/kg bw/day revealed a statistical increase in plasma bilirubin. This result was in the absence of any increase in weight or histopathological correlation of the liver and is considered inconclusive.

No toxicologically significant effects were demonstrated in animals treated with 150 or 25 mg/kg bw/day and based on these results, the No Observed Effect Level (NOEL) was established as 150 mg/kg bw/day in this study.

Irritation and Sensitisation
Based on the effects observed in a skin irritation study in rabbits, the notified chemical is considered to be slightly irritating to skin as it had caused discolouration during the first 3 days. All effects observed were reversible.

Based on the ocular lesions observed in an eye irritation study in rabbits the notified chemical would only be classified as slightly irritating. All effects observed were reversible

The notified chemical is not considered to be a sensitiser.

Mutagenicity
The notified chemical was negative in two independent Ames tests and considered to be non-clastogenic in two independent *in vitro* chromosome aberration tests in Chinese hamster lung cells.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical as introduced (0.5 –7%) is unlikely to be a skin irritant but may be a slight eye irritant. Ocular exposure to the notified chemical is not expected during usual conditions of use in the office environment and the risk of adverse local effects is considered to be low.

9.2.5. Public health – risk characterisation

As with office workers, ocular exposure to the notified chemical is not expected and hence the risk of eye irritation effects is considered to be low. Due the low and intermittent exposure expected the risk of adverse systemic effects is also considered to be low.

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

10.1. Hazard classification

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

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of an 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 an 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

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.

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.

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