File No: LTD/1302

June 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

FJM-001B in Brother LC51M

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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Director
NICNAS

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FULL PUBLIC REPORT

FJM-001B in Brother LC51M

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Brother International (Aust) Pty Ltd (ABN 17 001 393 835) of 7 Khartoum Rd, North Ryde, NSW, 2113.

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

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

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

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

Dissociation constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
UK 2003

2. IDENTITY OF CHEMICAL

MARKETING NAME
FJM-001 B

METHODS OF DETECTION AND DETERMINATION

METHOD Identity confirmed by Infrared, ^{1}H-NMR and UV/Vis spectroscopy. The purity and nature of impurities were determined by High Perfomance Liquid Chromatography (HPLC) and Liquid chromatography/Mass Spectroscopy (LC/MS).

Remarks Reference Spectra provided

3. COMPOSITION

DEGREE OF PURITY
> 75%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Although the hazardous properties of some impurities are not known, these were present in samples used for toxicity testing.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported in to Australia as an ingredient in ink in sealed inkjet print cartridges.

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 an ingredient in ink (<10%) in inkjet cartridges.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The inkjet cartridges will be stored in NSW prior to distribution.

TRANSPORTATION AND PACKAGING
The notified chemical is imported in sealed Inkjet print cartridges. Print cartridges will be individually packaged in cardboard boxes and then imported into Australia in master cartons. The volume of the ink in the Inkjet print cartridge is 800mL. The master cartons/boxes containing the Inkjets will be delivered to large business users by road transport.

5.2. Operation description
No manufacturing, reformulation, filling or refilling of cartridges will occur in Australia. When replacing ink cartridges, the public, office staff or a trained engineer will follow replacement procedures recommended by the manufacturer. This involves removing the seal tape and inserting the cartridge into printers. Service engineers may be involved in maintenance of the printer from time to time.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Storage/transport workers	10	4 hours/day	70 days / year
Service Engineers	100	6 hours / day	240 days /year
Office workers	1000	<0.1 hours / day	intermittent

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

Office staff and service engineers may be intermittently exposed to the notified chemical (<10%) in printer ink via skin contact when replacing the spent cartridges, cleaning paper jams or during maintenance and servicing. The service engineers typically will wear gloves and receive appropriate training in servicing techniques.

Contact with paper printed with the ink containing the notified chemical is unlikely to result in dermal exposure as the chemical will be bound within the matrix of the paper and become inert, except if the

paper or other substrate is handled before the ink has dried. Dermal and possible ocular exposure could also occur when handling faulty or ruptured cartridges.

When the cartridge is used, no discrete particles of the notified chemical are released as the cartridge is contained within the body of the ink jet printer and the distance between the cartridge head and paper is small (<1mm) so that the chance of air borne dispersal of the ink is negligible. Instead, droplets of ink solution containing the substance are deposited on paper. Together with the low volatility of the notified chemical in the ink, inhalation exposure is unlikely. Ocular exposure is also expected to be unlikely, as the ink is only released in minute amounts within the confines of the printer.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Printer ink will be imported in ready-to-use cartridges (containing <10% notified chemical). No release is expected as manufacturing and reformulation of the ink containing the notified chemical will not take place in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity, container and packaging specifications would limit the extent of release.

RELEASE OF CHEMICAL FROM USE

The ink cartridges are designed to prevent leakage and will not open during transport, use, installation or replacement. Therefore, release of ink containing the notified chemical to the environment is not expected under normal conditions of use. Spills during installation and replacement will be contained with absorbent and disposed of in landfill.

Cartridges are contained within the printer until the contents are used then they are removed and sent to a recycling and disposal centre. The cartridges will then be broken down in to component parts for recycling. Residual ink (<2% of the notified chemical) left in empty cartridges will be separated from the cartridge and incinerated during the recycling of the cartridges.

Most of the notified chemical (>98%) will be bound to the printed paper, which will be disposed of to landfill, recycled or incinerated. Recycling of treated paper may result in the release of a proportion of the notified chemical to the aquatic compartment. Waste paper is repulped using a variety of chemical treatments, which result in fibre separation and ink detachment from the fibres. The waste is expected to go to trade waste sewers. Approximately 50% of the ink printed on paper will enter paper recycling of which a proportion of the ink is expected to be recovered during recycling. While most may partition to water, due to the low percentage of the notified chemical in these inks and the widespread use, release to the aquatic compartment from any given recycling plant will still be low based on worst case assumptions. Any chemical absorbed to sludge during recycling process will be disposed of to landfill.

5.5. Disposal

The total import volume of the notified chemical will ultimately be disposed as normal office/domestic waste that will end up in either landfill or be incinerated. Some waste paper printed with the ink may be disposed of directly to landfill with the notified chemical bound to the paper. Some will enter the paper recycling process. Used cartridges will be sent to recycling and disposal centres. The cartridges will be broken down into component parts for recycling. Residual ink (< 2% of the notified chemical) left in the empty cartridges will be separated from the cartridges and incinerated during the recycling of the cartridges.

Notified chemical that is incinerated is expected to thermally decompose to form predominantly simple organic compounds and various salts. Similarly, notified chemical that is disposed of to landfill should eventually degrade.

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. However, it is expected that the public will be using the printer less often than workers.

6. PHYSICAL AND CHEMICAL PROPERTIES

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

Melting Point/Freezing Point > 360 ºC

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

Boiling Point > 360 ºC

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Test not conducted as the substance decomposes prior to melting at 360ºC
TEST FACILITY SPL (2003a)

Density 1490 kg/m^3 at 20 ºC

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

Vapour Pressure <1.9 x 10^{-8} kPa at 25ºC

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure at 25ºC was determined using a vapour pressure balance and linear regression analysis. This imposes a slope of –1500°K (an in-house value for the shallowest slope) on a chosen data point such as the reading at 193ºC for the test sample of the notified chemical considered being under vacuum for the longest period prior to the test and so degassing would have been the most complete. The value obtained by this method is expected to be the maximum.
TEST FACILITY SPL (2003c)

Water Solubility 514-537 g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask method was used, however, no analysis could be performed due to the high solubility of the notified chemical producing unfilterable mixtures and thus the water solubility was estimated based on visual inspection.
TEST FACILITY SPL (2003a)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*$t_{½}$ <hours>*
4	50	>120
7	50	>120
9	50	>120

Remarks The preliminary test showed less than 10% hydrolysis (by HPLC) after 5 days at 50°C in buffers of pH 4, 7 and 9, which is estimated to be equivalent to a half-life of >1 year at 25°C at any pH.
TEST FACILITY SPL (2003b)

Partition Coefficient (n-octanol/water) log Pow < -3.03 at 20°C

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks No deviations from the test protocol (Shake Flask Method) were reported.
TEST FACILITY SPL (2003a)

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

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge Using HPLC.
Remarks Test was performed using the HPLC screening method at pH 7. The notified chemical eluted before the standard solution of acetanilide, indicating it is highly mobile in soil or sediment.
TEST FACILITY SPL (2003b)

Dissociation Constant Not determined

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

Surface Tension 69.7 mN/m at 20 °C

METHOD EC Directive 92/69/EEC A.5 Surface Tension.
Remarks By the ISO 304 ring method, the surface tension of a 1.03 g/L solution of the notified chemical was determined with the result not being corrected using the Harkins-Jordan correction table as the correction was not considered applicable to the apparatus used. The notified chemical is not a surface active substance.
TEST FACILITY SPL (2003b)

Particle Size

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

Range (μm)	*Mass (%)*
<100 (inhalable)	14.7%
<10 (respirable)	0.9%

Remarks The sieve method was used as a screening test followed by the cascade impactor method for the definitive test.
TEST FACILITY SPL (2003b)

Flash Point Not determined

Remarks The notified chemical is a high melting point solid.

Flammability Not highly flammable

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

Remarks The notified chemical failed to ignite in the preliminary test during the two minutes the Bunsen flame was applied, and thus obviated the need to perform the main test.

TEST FACILITY SPL (2003d)

Autoignition Temperature >400 °C

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

TEST FACILITY SPL (2003c)

Explosive Properties Not explosive

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

Remarks The notified chemical was negative in tests of both mechanical sensitivity (BAM fall hammer and friction tests) and thermal sensitivity (Koenen steel tube test).

TEST FACILITY SPL (2003c)

Oxidizing Properties Not expected to be oxidising

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

Remarks The notified chemical does not contain groups predicted to have oxidising properties.

TEST FACILITY SPL (2003c)

Reactivity Not determined

Remarks Expected to be stable under normal conditions of use. Impurities present are hydrolytic derivatives of the notified chemical.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity, LD50>2000 mg/kg bw
Rat, acute dermal	low toxicity, LD50>2000mg/kg bw
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Mouse - Local Lymph Node Assay	evidence of sensitisation.
Rat, oral repeat dose toxicity – 28 days	NOEL=250mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley CD
- Vehicle: Distilled water
- Remarks – Method: No significant protocol deviations

RESULTS

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

- LD50: >2000 mg/kg bw
- Signs of Toxicity: All animals showed dark red staining of the fur throughout the 14-day study period and red stained faeces and/or dark red stained urine up to three days after dosing. Weight gain was as expected.
- Effects in Organs: Dark liver and kidneys (stained red) were noted at necropsy in all animals.

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

TEST FACILITY — SPL (2003e)

7.2. Acute toxicity – dermal

TEST SUBSTANCE — Notified chemical

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test
- Species/Strain: Rat/Spraque-Dawley CD
- Vehicle: Distilled water (moistened)
- Type of dressing: Semi-occlusive
- Remarks – Method: No significant protocol deviation

RESULTS

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

- LD50: >2000 mg/kg bw

Signs of Toxicity - Local	No signs of dermal irritation were noted.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted. All animals showed expected weight gains.
Effects in Organs	No macroscopic abnormalities were noted at necropsy.
Remarks – Results	Red coloured staining was noted at the treatment sites of all animals after 1 day dosing, of all females 2-5 days after dosing, and of one female 6 days after dosing. These were considered to prevent the evaluation of erythema.
CONCLUSION	The notified chemical is of low acute toxicity via the dermal route.
TEST FACILITY	SPL (2003f)

7.3. Irritation – skin

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

RESULTS

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

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
NA, not applicable.

Remarks – Results	There is no evidence of skin irritation or corrosion during the study. Pink coloured staining was noted at two treated skin sites, however, this was considered not to affect evaluation of skin reactions.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	SPL (2003g)

7.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	14 days
Remarks – Method	No significant protocol deviation

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.0	2.0	2.0	2	<14d	0
Conjunctiva: chemosis	2.3	2.3	2.3	3	<14d	0
Conjunctiva: discharge	2.3	2.3	2.0	3	<14d	0
Corneal opacity	1.0	1.0	1.0	1	<7d	0
Iridial inflammation	1.0	1.0	1.0	1	<7d	0

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

Remarks – Results

Pink-colored staining of the fur was noted around all treated eyes throughout the study. Pink-colored staining of the cornea and/or conjunctiva was observed in all treated eyes up to 72 hours observation and on occasions prevented the evaluation of conjunctival redness.

Area of conjunctival hemorrhage approximately 1mm x 3mm located on the lower edge of the nictitating membrane was noted in one rabbit at the 48 and 72 hours observations. Pale appearance of the nictitating membrane was noted in one rabbit at the 72 hours and day 7 observations.

Treated eyes appeared normal at the 14-day observation.

CONCLUSION The notified chemical is irritating to the eye.

TEST FACILITY SPL (2003h)

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

TEST SUBSTANCE Notified chemical

METHOD OECD 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mice/CBA CaBkl
Vehicle Dimethyl Sulphoxide (DMSO)
Remarks – Method No significant protocol deviation. The vehicle was chosen as it produced the highest concentration that was suitable for dosing.

RESULTS

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

*α-hexylcinnamaldehyde in 4:1 acetone/olive oil

Remarks – Results

The notified chemical showed a stimulation index (SI) of >3 with the 25% solution, thus is considered as a sensitiser under the conditions of the test. Red coloured staining of the fur was noted in all test animals during the study. No signs of systemic toxicity or deaths were observed. Body

weight changes were comparable between the test and control animals. An EC value was not calculated.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY SPL (2003i)

7.6. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD Guideline of Japanese Chemical Substance Control Law "Method for the test on New Chemical Substances - Repeated Dose (28 Days) Toxicity in Mammalian Species"

Species/Strain Rat/Wistar

Route of Administration Oral – gavage

Exposure Information Total exposure days: 28 days
Dose regimen: 7 days per week
Post-exposure observation period: 14 days (for high dose and control groups only)

Vehicle Purified water

Remarks – Method No significant protocol deviation from the OECD TG 407.
A dose finding study using 5 males and 5 females of Wistar strain rats was performed. In the results, faeces coloured red, same to the dosing solution, were seen in 1000 mg/kg group, but urine showed normal colour. No changes were seen in general conditions or body weight, but lowered values of erythrocyte count, haemoglobin concentration, albumin, total cholesterol, and triglyceride, and decrease tendency of the liver and kidney weights (questionable according to the main study, but no details is provided in the report) were seen in both 300 and 1000 mg/kg groups. Therefore, 3 doses (60, 250, and 1000 mg/kg) were selected.

RESULTS

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

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

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

Faeces coloured red (similar colour to the dosing solution) were seen throughout the administration period in the high dose group, after 2 days in the mid dose group, and after 11 days in the low dose group. Staining of perianal region was also observed in high dose after 2 days. In the recovery group, the faecal coloration and perianal staining disappeared on day 3 and 5 onwards respectively after the end of administration.

Changes observed in the high dose group only include reduced body weight gain from the beginning of

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

Laboratory Findings – Haematology, Clinical Chemistry, Urinalysis

Haematology

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

Clinical Chemistry

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

Urinalysis

No remarkable changes were seen in all does groups or in the recovery groups.

Effects in Organs

Pathological examination

At necropsy, no remarkable changes were observed in males or females of each dose group at the end of treatment, however, the contents of the digestive tract showed red coloration, and the digestive tract was macroscopically scrutinized to confirm the presence or not of hemorrhage, and lesions such as mucosal exfoliation, hyperemia, or hemorrhagic trace were seen. Slight red coloration of the renal cortex was seen in all animals of the high dose group. In the recovery group, the coloration of renal cortex and digestive tract observed was not disappeared completely.

Relative weights of the heart and testes in the high dose group were increased. Adrenals and uteri showed increase in absolute and relative weights. These changes were not dose related and considered to be non-specific, probably relating to the reduced body weight gain. In the recovery group, similar changes to those observed at the end of administration period in the heart and testes were seen. Relative weights of the liver, spleen, pituitary, and epididymides were increased, however, these were minor and not dose related and also considered to be non-specific. There was a minor decrease in absolute thymus weight in females, but this was not considered to be treatment related. However, a dose related increase of the relative kidney weight (statistically significant in the high dose group only) in both males and females was observed which persisted in the recovery group. This change is considered treatment related.

Histopathological examination

Small round cell infiltration into portal region (slight to moderate degree) in the liver, and vacuolar degeneration of tubular epithelium (slight) in the kidney were seen in all high dose males and females. These changes were considered treatment related as none of them were seen in the control group. In the recovery group, the infiltration into portal region in the liver was not seen, while the degeneration of tubular epithelium in the kidney became minor both in males and females, suggesting that these effects may be reversible. These histopathological changes correspond to the macroscopic findings of red coloration of the renal cortex and the relative kidney weight change observed. Small granulation foci in the liver observed in the high dose animal were seen in a similar degree to the control group, and no differences were seen in incidence or severity

between these two groups, and thus the effect was not considered treatment related.

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

TEST FACILITY Saitama Laboratory (2002)

7.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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

Species/Strain	*S. typhimurium*: TA98, TA100, TA1535, TA1537 *E. coli*: WP2 uvrA
Metabolic Activation System	S9 fraction from Phenobarbital and β-naphthoflavone induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 313, 625, 1250, 2500, 5000 µg/plate b) Without metabolic activation: 313, 625, 1250, 2500, 5000 µg/plate.
Vehicle	Sterilised distilled water
Remarks – Method	A dose-range study was performed. No significant protocol deviation. Test 2 was conducted on TA1537 only due to control issues in Test 1. For this class of chemicals the following method may have been more appropriate: • pre-incubation method • use of a reductive metabolic activation system

RESULTS

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

Remarks – Results The notified chemical did not induce a 2-fold or more increase in the number of revertant colonies compared to the negative control, either with or without metabolic activation. In test 1, the revertant colony counts on the positive control plates of TA1537 with metabolic activation were 243 (mean), which were out of the control range of 260-697 of the testing facility, and thus they were not included in the analysis, but those obtained in the retest were used (Test 2).

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

TEST FACILITY ME (2002a)

7.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.

Species/Strain Chinese hamster

Cell Type/Cell Line pulmonary fibroblast (CHL/IU)

Metabolic Activation System S9 fraction from phenobarbital and β-naphthoflavone induced rat liver.

Vehicle Sterilised physiological saline

Remarks – Method This study was carried out by a short-term treatment regime (with and without S9) and a continuous treatment regime (1.5 and 3.0 cell cycle lengths). The treatment regime for 1.5 and 3.0 cell cycle lengths was adopted to Ishidate's method (Ishidate, 1987).

A cell growth inhibition was conducted using the test substance at the dose levels determined using a common ratio of 2 both in the short and continuous treatment regimes, including 5 mg/kg as the highest dose.

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

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (mg/mL) Resulting in:*			
	*Cytotoxicity in PreliminaryTest**	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	≥1.3	≥1.1	>2.2	Negative
Absent				
Test 1	≥1.3	≥1.3	>2.5	Negative
Test 2	≥0.63	≥0.63	>1.3	Negative
Test 3	≥0.16	≥0.16	>0.31	Negative

* dose that approximately 50% cell growth inhibition was found from the cell growth inhibition study.

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

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

TEST FACILITY ME (2002b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD

OECD TG 301 C Ready Biodegradability: Modified MITI Test (I). Biodegradability test of a chemical substance by microorganisms, as prescribed in No. 5 of "Kanhogyo", No. 615 of "Yakuhatsu" and No. 392 of "49 Kikyoku" dated July 13, 1974

Inoculum	Standard activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	HPLC and TOC method
Remarks – Method	The concentrations of the test material and reference (aniline) for testing were 100 mg/L. Test temperature: 25±1°C. Biodegradation was calculated from BOD (biochemical oxygen demand), TOC (total organic carbon) and HPLC analysis of test substance.

RESULTS

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

Remarks – Results	No biodegradation was observed for the notified chemical. The percentage degradation calculated from BOD and TOC analysis was 0% and 1% on average, respectively. The residual rates calculated from HPLC analysis were 99%-100% on average. The percent degradation of Aniline on Day 7 was 63%, and it was, therefore, confirmed that the study conditions were valid.

CONCLUSION: The notified chemical cannot be classed as ready biodegradable under the conditions of this study.

TEST FACILITY: Fuji Film Co. (2003)

8.1.2. Bioaccumulation

A bioaccumulation study was not conducted. As Log Pow is very low (-3.03), and water solubility as well as molecular weight are high. The potential for bioaccumulation is very low.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD
- Species: Rainbow trout (*Oncorhynchus mykiss*) [juvenile].
- Exposure Period: 96 hours
- Auxiliary Solvent: None
- Water Hardness: 100 mg $CaCO_3$/L
- Analytical Monitoring: Chemical analysis at 0, 24, 28, 96 hours.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0		0
1.0		10	0	0	0		0
1.8		10	0	0	0		0
3.2		10	0	0	0		0
5.6		10	0	5	6		6
10		10	10	10	10		10

- LC50: 5.3 mg/L at 96 hours (95% confidence level of 4.5 – 6.3 mg/L).
- NOEC: 3.2 mg/L at 96 hours.
- Remarks – Results: No mortalities were observed at test concentrations of less than 3.2 mg/L. After 96 h, 60 and 100% mortality was observed at test concentrations of 5.6 and 10 mg/L, respectively. A sub-lethal effect was observed at the test concentration of 5.6 and 10 mg/L. This response was the presence of a moribund fish after 1 h and 40 min exposure at 10 mg/L, and after 29 h and 30 min exposure at 5.6 mg/L.

  Analysis of test solutions at 0, 24, and 96 hours showed measured concentrations to range from 92-106% of nominal, so the results are based on these.

CONCLUSION: The notified chemical is toxic to Rainbow trout.

TEST FACILITY: SPL(2003j)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Analytical monitoring at 0 and 48 hours showed that the notified chemical was stable during the tests. Results are based on nominal concentrations.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
1.8	1.84	10	0	0
3.2	3.21	10	0	0
5.6	5.68	10	0	0
10	10.1	10	0	0
18	16.8	10	0	0
32	34.4	10	0	2
56	55.7	10	0	3
100	102	10	2	8
180	162	10	3	10

LC50	60 mg/L at 48 hours (95% confidence level of 51-72 mg/L)
NOEC (or LOEC)	18 mg/L at 48 hours
Remarks – Results	No effects were observed at test concentrations of less than 18 mg/L. These solutions were clear and pink while those greater than 18 mg/L were clear red solutions of increasing colour density. After 48 h, 50 % of the population showed effects at the nominal test concentration of 60 mg/L of the notified substance, with a 95% confidence limit.
CONCLUSION	The notified chemical is harmful to *Daphnia magna*.
TEST FACILITY	SPL (2003k)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	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, 320 mg/L
Concentration Range Actual	77 -102%
Auxiliary Solvent	None
Analytical Monitoring	Standards and test solutions were tested by HPLC. These were 85-92% of nominal at test initiation and declined slightly by 72 h. Samples of the algal populations were measured for each control group and treatment group, using a Coulter® Multisizer II Particle Counter.
Remarks – Method	Duplicate experiments (A and B) were performed to differentiate growth effects between toxicity and reduced light causes. Experiment A: Algae were exposed to test material in a flask enclosed from above by a petri dish containing culture medium only. Inhibition was due to a combination of toxicity and reduction in light intensity. In Experiment B, algae were not exposed to the test material in the flasks, but the flasks were enclosed by petri dishes containing the culture media and the test material. Therefore, inhibition of algal growth was due to a reduction in light intensity alone. The difference between Experiments A and B inhibition values is presumed to be due to the toxic effect of the test material on algal cells. Mean cell density in Expt. A was $9.47X10^3$ cells/mL (initial) and $4.80X10^5$ cells/mL (72 hours). Mean cell density in Expt. B was $8.19X10^3$cells/mL (initial) and $3.93X10^5$ cells/mL (72 hours). Constant illumination and stirring. Temperature 24±1 °C. pH 7.4 -7.6.

RESULTS

Biomass		*Growth*	
EbC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
Expt A: 27.0 mg/L	2.6 mg/L	180 mg/L	2.6 mg/L
Expt B: 43.0 mg/L	10 mg/L	94 mg/L	10 mg/L

Remarks – Results	Given that significant differences (greater than 10%) in the inhibition values between Experiments A and B were observed, it was considered that the effect of the notified chemical on algal growth was not only due to a reduction in light intensity, but also due to the intrinsic toxic properties of the chemical. Therefore, for classification purposes the results determined from Experiment A should be used.
CONCLUSION	The results indicated the combined toxic nature of the notified chemical and the effects of reduction in light intensity. The notified chemical is harmful to *Scenedesmus subspicatus.*
TEST FACILITY	SPL (2003l)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical, 02MA06
METHOD	EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sewage
Exposure Period	3 hours
Concentration Range Nominal	10, 32, 100, 320, 1000, 3200 mg/L
Remarks – Method	Following a preliminary range-finding test, activated sludge was exposed in the definitive test to an aqueous solution of the test material at concentrations of 10, 32, 100, 320, 1000 and 3200 mg/L for a period of 3 hours at 21°C with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3,5-dichlorophenol.
RESULTS	
IC50	160 mg/L (3 hours)
NOEC	10 mg/L (3 hours)
Remarks – Results	None
CONCLUSION	The effect of the notified chemical on the respiration of activated sludge micro-organisms gave a 3-hour EC50 of 160 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 10 mg/L. The validation criteria for the control respiration rates and reference material EC50 values were satisfied, thus validating the test.
TEST FACILITY	SPL (2003m)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Manufacture, reformulation and packaging into end-use containers occurs overseas, and release is not expected. After use, printed paper may be disposed of by incineration, to landfill or be recycled. The notified chemical disposed of to landfill may be mobile, however, the low proposed annual import volume, and diffuse release throughout Australia will mitigate any potential exposure while the notified chemical slowly degrades.

In Australia, approximately 50% of printed paper is recycled. The following Predicted Environmental Concentration calculation assumes this 50% recycling, and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50.000%	
Annual quantity of chemical released to sewer	500.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.37	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.33	µg/L
PEC - Ocean:	0.03	µg/L

9.1.2. Environment – effects assessment

Aquatic ecotoxicity data were provided for three trophic levels, with aquatic invertebrates demonstrating the highest level of sensitivity to the notified chemical. The following Predicted No-Effect Concentration has been calculated using an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	5.30	mg/L
Assessment Factor	100.00	
PNEC:	53.00	µg/L

9.1.3. Environment – risk characterisation

Based on the above PEC and PNEC values, the following Risk Quotient has been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.33	53	0.006
Q - Ocean:	0.03	53	0.001

This indicates that the current import volume and use pattern is not expected to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

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

Office staff and service engineers may be intermittently exposed to the notified chemical (<10%)

in printer ink via skin contact when replacing the spent cartridges, cleaning paper jams or during maintenance and servicing. The service engineers typically will wear gloves and receive appropriate training in servicing techniques.

Contact with paper printed with the ink containing the notified chemical is unlikely to result in dermal exposure as the chemical will be bound within the matrix of the paper and become inert, except if the paper or other substrate is handled before the ink has dried. Dermal and possible ocular exposure could also occur when handling faulty or ruptured cartridges.

Workers' exposure via inhalation is unlikely due to the low volatility of the notified chemical and it is not expected that the notified chemical be released during printing as the cartridge is confined within the body of the ink jet printer.

9.2.2. Public health – exposure assessment

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. However, it is expected that the public will be using the printer less frequent than workers.

9.2.3. Human health – effects assessment

Toxicological data for the notified chemical for the following health end points were submitted:

- acute oral and dermal toxicity
- primary dermal irritation
- eye irritation
- skin sensitisation (LLNA)
- 28-day subacute oral toxicity (gavage)
- genotoxicity

Acute toxicity
The notified chemical is of low acute oral and dermal toxicity in rats (LD50 >2000 mg/kg).

Irritation and sensitisation
The notified chemical is not a skin irritant. An eye irritation and a LLNA study conducted under the OECD Test Guidelines showed moderate to severe eye irritation (scatter or diffuse corneal opacity, iridial inflammation and conjunctival irritation) and skin sensitisation. The severity of the eye irritation meets the criteria for hazard classification.

Repeated dose toxicity
A 28-day oral repeated study found a number of treatment-related changes in haematology and clinical chemistry parameters in the high dose group (1000 mg/kg/day). Small round cell infiltration into portal region (slight to moderate degree) in the liver, and vascular degeneration of tubular epithelium (slight) in the kidney were seen in all high dose males and females. These changes were considered treatment related as none of them were seen in the control group. The infiltration into portal region in the liver was not seen in the recovery group, while the degeneration of tubular epithelium in the kidney became minor both in males and females, suggesting that these effects may be reversible. The histopathological change in the kidney corresponds to the macroscopic finding of the treatment-related relative kidney weight increase. The NOAEL was established as 250 mg/kg bw/day in both male and female in this study, which does not meet the criteria for hazard classification.

Mutagenicity
A bacterial reverse mutation test and a mammalian chromosomal aberration test in vitro conducted under the OECD Test Guidelines indicate that the notified chemical does not have mutigenicity potential.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004). The classification details are:

R36 Irritating to eyes

R43 May cause sensitisation by skin contact

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is a hazardous chemical and can cause eye irritation and skin sensitisation.

The risk of the eye irritation and skin sensitisation during transportation and storage is low due to the negligible workers' exposure. Emergency procedures are in place to minimise exposure in the event of accidental spills/breaches.

The risk of eye irritation during the end use by office workers and customer service engineers is also expected to be low because of the concentration of the notified chemical in the printing ink (<10%) and limited potential for ocular exposure.

The risk of skin sensitisation during the end use exists, especially for the office workers who do not usually wear gloves when handing the ink cartridges such as replacing the spent cartridges and cleaning paper jams and when handling the paper or other substrate before the ink has dried. However, the risk should be limited due to the fully sealed cartridges, proper use instructions on product labels, and workplace regulatory labelling requirements for product containing Type I ingredients over the concentration cut-off (≥ 1% for skin sensitisation).

9.2.5. Public health – risk characterisation

Based on the similar use and exposure pattern to the workers, plus potentially less frequent exposure to the public than workers, the risk of the eye irritation to the public is not expected to be significant.

However, the risk of skin sensitisation exists during change of ink cartridges, handling printed paper before the ink is dried, and accidental faulty or rupture of cartridges. Appropriate consumer protections should be recommended to minimise the risk. The risk should be limited due to the fully sealed cartridges and proper use instruction on product labels. The risk would also be reduced by use of appropriate warning and safety directions on the label.

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

10.1. Hazard classification

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

R36 Irritating to eyes
R43 May cause sensitisation by skin contact

and

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

	Hazard category	***Hazard statement***
Health		
Eye irritation	2A	Cause severe eye irritation
Skin sensitisation	1	May cause an allergic skin reaction
Environment		
Acute	2	Toxic to aquatic life
Chronic	2	Toxic to aquatic life with long lasting effects

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is No Significant Concern to occupational health and safety under the conditions of the occupational settings described, provided products are adequately labelled and safety instructions are followed.

10.3.2. Public health

There is No Significant Concern to public health when used in printing ink contained in sealed cartridges, provided products are adequately labelled and safety instructions are followed.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the products containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:

Risk phrases:
- R36 Irritating to eyes
- R43 May cause sensitisation by skin contact

Safety phrases:
- S24 Avoid contact with skin
- S25 Avoid contact with eyes
- S37 Wear suitable gloves

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 1%: R43
  - ≥ 20%: R36, R43

- The National Drugs and Poisons Scheduling Committee (NDPSC) should consider the notified chemical for listing on the SUSDP.

- Products containing the notified chemical and available to the public must carry safety directions and warning statements on the label consistent with the following:
  - May cause allergy
  - Avoid contact with skin
  - Wash hands after use

Health Surveillance

- As the notified chemical is a health hazard, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in ink cartridges, especially during handling faulty or ruptured cartridges:
  - Avoid skin and eye contact
  - Wear suitable gloves

- 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.

Public Health

The following measures should be taken by the cartridge manufacturers to minimise public exposure to the notified chemical:

- The design of the ink cartridges should minimise the potential for leaks or ruptures.
- The product label should include appropriate use and safety directions.

Environment

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical; or
- the concentration of the notified chemical exceed 10%.

or

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

The Director will then decide whether secondary notification is required.

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