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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

MJR6580

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Brother International (Aust) Pty Ltd (ABN: 17 001 393 835)
7 Khartoum Rd
North Ryde NSW 2001

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:
Chemical Name
CAS No.
Other Names
Molecular and Structural Formulae
Molecular Weight
Spectral Data
Non-hazardous Impurities
Purity
Import Volume
Formulation details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour pressure
Partition coefficient
Hydrolysis
Adsorption/desorption

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC/653 (2004)

NOTIFICATION IN OTHER COUNTRIES
Japan METI (2202)
UK HSE (2002)
US EPA (2002)
Switzerland BUWAL (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MJR6580

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, UV-Visible spectroscopy, NMR and MS spectrometry.
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
80–90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical is imported in ink-jet cartridges at a concentration of 1-5%

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 will be used as a component of printer inks. It will be imported in ink-jet cartridges (1-5% notified chemical) for use in workplace and personal computer printers.

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 before their distribution to offices and retailers of office supplies nationwide.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in ready to use ink-jet printer cartridges (size 15 mL). No reformulation or repackaging will take place.
After import, the cartridges are transported by land and are expected to be stored in a warehouse under cool, dry conditions, away from flames and sources of ignition.

5.2. Operation description

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

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

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage Workers	5-10	2-3 h	10-20 days/yr
Service Technicians	10-20	0.5 h	100 days/yr
Inkjet Operators	>1000	0.1 h	20 days/yr

Exposure Details

Transport and Storage

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

End-Use

Inhalation exposure is unlikely, as the notified chemical is of low volatility in a liquid preparation and during the printing process, mist emission of the non-volatile components of the ink from the printer is expected to be low. Ocular exposure is also expected to be unlikely, as the ink is only released in minute amounts within the confines of the printer.

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

Service technicians may be exposed to the ink (containing 1-5% notified chemical) during repair and cleaning of ink jet printers. Exposure is expected to be primarily dermal.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical is imported into Australia in ready for use cartridges. No reformulation takes place in Australia and no release is expected, except from spills where the cartridges are breached.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical (95%; < 950 kg) will be used in its designated use as ink on paper. At the end of the printed materials' useful lives it will be disposed of by landfill or incineration; or recycled. Approximately 50% of printed material is recycled in Australia (NOLAN - ITU). During recycling the paper products are de-inked with the majority the inky residue being used as soil conditioner or possibly incinerated. The remainder will be flushed to the sewer.

Approximately 5% (<50 kg) is expected to remain in the ink jet cartridges. These are expected to be disposed of to landfill; or recycled, or be sent to the manufacturer for remanufacture. The notifier estimates that approximately 50% of ink jet cartridges (< 25 kg of notified chemical) will be sent to landfill. During recycling of ink cartridges, the ink containing the notified chemical is expected to be incorporated into products containing low grade inks.
(http://www.planetark.org.au/campaignspage.cfm/newsid/42/newsDate/5/story.htm)
These products are likely to be disposed of at the end of their useful lives.

Remanufacture is likely to occur at the same location as the original manufacture of the ink jet cartridges and therefore this is likely to occur outside of Australia.

5.5. Disposal

Paper products having ink containing the notified chemical printed thereon are likely to be disposed of to landfill or possibly incinerated. If the paper products are recycled the ink will be disposed of as soil conditioner, possibly by incineration or to the sewer.

Empty cartridges containing ink residue are likely to be disposed of to landfill or recycled into products containing low grade inks. These products are likely to be disposed of to landfill at the end of their

useful lives.

5.6. Public exposure

The notified substance is a component used in inkjet printers. The public will be potentially exposed to the notified chemical during use, however it is expected to be fixed to the paper. Limited exposure may occur while changing inkjet cartridges, however this will be relatively infrequent and should only result in very limited exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Reddish brown lumpy solid

Melting Point/Freezing Point >250 °C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined by Differential Scanning Calorimetry. The notified chemical decomposes at 250-350°C prior to melting. Statement of GLP.
TEST FACILITY	Covance Laboratories (2001a)

Boiling Point >250 °C

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The notified chemical decomposes at 250-350°C prior to boiling. Statement of GLP.
TEST FACILITY	Covance Laboratories (2001a)

Density 1616 kg/m^3 at 20°C

METHOD	Procedure conformed with OECD TG 109 Density of Liquids and Solids and EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined by gas comparison pyknometer Statement of GLP. The measured temperature was 19.9°C. The relative density of the free acid was also measured and was found to be 1.6653 at 23.5 ± 0.5°C (Safepharm Laboratories (1995a))
TEST FACILITY	Covance Laboratories (2001b)

Vapour Pressure 3.8×10^{-19} kPa at 25°C (free acid)

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Measured for the free acid. Triplicate runs were performed using a vapour pressure balance at temperatures between 215 – 250°C.
TEST FACILITY	Safepharm (1995b)

Surface Tension 72.7 mN/m at 20°C

METHOD	OECD TG 115 Surface Tension of Aqueous Solutions. EC Directive 92/69/EEC A.5 Surface Tension.
Remarks	Determine in a 9% saturated solution in water with a tensiometer using the ring method. The notified chemical is not surface active. Statement of GLP.
TEST FACILITY	Covance Laboratories (2001a)

Water Solubility 277 g/L at 20°C

METHOD	Procedure conformed with OECD TG 105 Water Solubility and EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Flask Method. The resultant pH was 7.4. A test was also conducted on the free acid; its solubility was 93.1 mg/L. (Safepharm Laboratories (1995a))
Analytical method: HPLC

TEST FACILITY Covance Laboratories (2001a)

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)*	*t½ days*
4	25	220
7	25	> 365
9	25	> 365

Remarks The hydrolysis as a function of pH test was performed on the free acid of the notified chemical. At pH 7 and 9, less than 10% hydrolysis was observed after 120 hrs at 50°C. The observed half life at pH 4 at 50°C and 40°C was 206 and 703 h respectively.

TEST FACILITY Safepharm Laboratories (1995a)

Partition Coefficient (n-octanol/water) log Pow = - 2.11 at 21.5 ± 0.5°C (free acid)

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient. Shake Flask

Remarks The partition coefficient was performed on the free acid of the notified chemical. A preliminary shake flask test was performed. The result showed that the Log Pow ~ -1. Three duplicate tests were performed with n-octanol/water ratios of 2:1, 1:1 and 1:2. Methanol was used as an auxiliary solvent. Standards were prepared for the organic phase using methanol:water saturated n-octanol (50:50). Similarly standards were prepared for the aqueous phase using methanol: n-octanol saturated water (50:50). The concentration of the test substance was measured by HPLC against the calibration standards. The notified chemical being the salt is likely to show even greater affinity for the aqueous phase and hence the log Kow is likely to be even lower.

TEST FACILITY Safepharm Laboratories (1995a)

Adsorption/Desorption – screening test log K_{oc} = 4.15 temperature not specified.

METHOD Based on OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)*
1 Wick Series	0.6	4.8	3.37×10^4
2 Bearsted Series	1.8	5.5	6.27×10^3
3 Wick Series	0.6	7.3	2.76×10^3

Remarks Three soils labelled 1, 2 and 3 were collected. These were classified as typical brown earth Wick Series, typical brown earth Bearsted series and typical brown earth Wick Series. The locations for collection were Warwick England, Leamington Spa England and Warwick England (UK). The cation exchange capacity (C.E.C) milliequivalents/100 g was 10.5, 14.5 and 10.5 respectively. The test was conducted on the free acid.

TEST FACILITY Safepharm Laboratories (1995a)

Dissociation Constant Not tested

Remarks The notified chemical will have multiple dissociation constants. At least one is expected to be less than 4, meaning that the chemical will remain in its dissociated form throughout the environmental range (pH 4 – 9). An equivalent conductivity

result of 371.36 – 1911.3 was supplied. Although no units were specified, it is expected that these were S/cm.

Particle Size Not determined

Remarks Test not conducted. The notified chemical is imported as an aqueous solution.

Flash Point Not determined

Remarks Test not conducted. The notified chemical is imported as an aqueous solution.

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical could not be ignited with a flame, did not melt, did not spark or emit smoke during the preliminary and main test.
Statement of GLP.
TEST FACILITY Covance Laboratories (2001a)

Autoignition Temperature 291°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks Test conducted up to 400ºC.
Statement of GLP.
TEST FACILITY Covance Laboratories (2001a)

Explosive Properties Not explosive (free acid)

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Measured using free acid. Based on this the notified chemical is alos predicted not to be explosive.
TEST FACILITY Safepharm (1995b)

Oxidizing Properties No oxidising properties (free acid)

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Measured using the free acid.
TEST FACILITY Safepharm (1995b)

Reactivity

Remarks The notified chemical is stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral	Notified chemical	LD50 >2000 mg/kg bw, low toxicity
Rat, acute dermal	Free acid form of the notified chemical	LD50 >2000 mg/kg bw, low toxicity
Rabbit, skin irritation	Free acid form of the notified chemical	non-irritating
Rabbit, eye irritation	Free acid form of the notified chemical	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	Notified chemical	no evidence of sensitisation
Rat, repeat dose <oral> toxicity – 28 days.	Free acid form of the notified chemical	NOEL = 40 mg/kg/day bw
Genotoxicity – bacterial reverse mutation	Notified chemical	non mutagenic
Genotoxicity – in vitro <test type>	Free acid form of the notified chemical	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:WI(Glx/BRL/Han)BR).
Vehicle	Purified water.
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	500	None
2	"	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity	At 2000 mg/kg bw: red/pink discolouration of faeces, urine, cage bars and liners due to staining by test article; piloerection and anogenital soiling observed in most animals, hunched posture, stained snout lethargy, exophthalmos and straub tail were observed in three or less animals. All rats achieved body weight gain during week 2 but all males and 1 female did not recover the bodyweight losses incurred during the pre-dose fast. All signs had reversed day 7. At 500 mg/kg bw: discoloured faeces.
Effects in Organs	None.
Remarks - Results	The LD50 cut-off estimated using the flow chart in annex 2d of the OECD TG423 would be ≥5000 mg/kg bw
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Covance (2001b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley.
Vehicle	Skin moistened with distilled water prior to application.
Type of dressing	Semi-occlusive.
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Isolated incident of small, superficial, scattered scabs; staining prevented scoring of erythema.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	Safepharm (1995d).

7.3. Acute toxicity – inhalation

Test not conducted

7.4. Irritation – skin

TEST SUBSTANCE	Free acid of the 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	Test substance moistened with distilled water.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	N/A	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	Pink staining was noted at all treated skin sites during the study. The

effect on the scoring of erythema not stated.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Safepharm (1995e).

7.5. Irritation - eye

TEST SUBSTANCE Free acid of the 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 (2 males, 1 female)
Observation Period 21 days.
Remarks - Method Statement of GLP.
No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	1.67	1.67	2	< 7 days	0
Conjunctiva: chemosis	0	1.33	1.33	2	< 7 days	0
Conjunctiva: discharge	0	0.67	0.33	3	< 48 hours	0
Corneal opacity	0	0.67	4	4	< 21 days	0
Iridial inflammation	-	-	-	-	-	0

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

Remarks - Results Iridial inflammation and conjunctival redness (at 1 hour only) were unable to be evaluated due to staining. Iridial inflammation was unable to be evaluated due to staining at times up to 72 hours and in 2 animals also at 7 days. Corneal opacity was severe in one animal at times up to 72 hours. Staining prevented the evaluation of conjunctival redness in all treated eyes at the 1 hour observation.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Safepharm (1995f).

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation test.

Species/Strain Guinea pig/Dunkin-Hartley.
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1% w/v
topical: 50% w/w (top dose tested)
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal injection, 5% (w/v in water)
topical application, 50% (w/w in Vaseline)

Signs of Irritation	Intradermal injection: The intradermal injections with Freund's Complete Adjuvant (with and without notified chemical) typically caused slight erythema. Scoring at nine sites in the test animals was precluded due to purple staining. The administration sites treated with notified chemical in water showed slight erythema in two animals, scoring at four sites was precluded due to purple staining. Intradermal injections of the vehicle alone exhibited no signs of irritation. Topical Induction: No erythema was observed in 6 test animals and assessment of the remaining 14 was not possible due to extensive staining. Slight erythema in 7 of 10 animals was observed when treated with the vehicle alone.
CHALLENGE PHASE	
1st challenge	topical application: 25% (w/w in Vaseline) topical application: 50% (w/w in Vaseline)
2nd challenge	topical application: not performed
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	25%	0/20	0/20	-	-
	50%	0/20	0/20	-	-
Control Group	25%	0/10	0/10	-	-
	50%	0/10	0/10	-	-

CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Covance (2001c).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	SPF Crj:CD(SD) rats.
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	Mixture of 100 parts of a 2% aqueous solution of potato starch and 2 parts Tween 80.
Remarks - Method	Statement of GLP. Deviations form the current protocol include: 1. Functional observations not conducted 2. Organ weights not measured: heart, thymus, epididymides 3. Histopath performed: heart, liver, spleen, kidneys, adrenals and testes (all non recovery animals, brain (one animal) kidney (recovery animals)

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	6/sex	0	None
II (low dose)	6/sex	40	None
III (mid dose)	6/sex	200	None
IV (high dose)	6/sex	1000	None
V (control recovery)	6/sex	0	None
VI (high dose recovery)	6/sex	1000	None

Mortality and Time to Death
All animals survived until scheduled necropsy.

Clinical Observations
Salivation in some males of the high dose group.

Food Consumption: Food consumption was increased in males of the mid and high dose group animals.

Body Weight: Body weight was increased in males of the mid and high dose group animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry: Significant elevated inorganic phosphorus in high dose males and calcium in high dose females which reversed during the treatment free recovery period.

Haematology: No significant findings.

Urinalysis: No significant findings.

Effects in Organs
Organ Weights: Increased absolute kidney weights in mid- and high dose females by 15% and 16%, respectively. Similar changes not observed in recovery group. Adrenal and testes weight was decreased significantly in males in the high dose group in the recovery group.

Macroscopic Findings: Reddish change in the kidneys of the high dose group (both sexes) and one male of the high dose recovery group was associated with the colour of the notified chemical.

Histopathological Findings: An increased incidence of slight to moderate eosinophilic granules in the proximal tubular epithelium in high dose males was observed in high dose males. The incidence and severity of this change showed no significant difference at the end of the recovery period. The changes to adrenal and testes organ weight was not accompanied by any histopathological findings.

Remarks – Results
None.

CONCLUSION
The No Observed Effect Level (NOEL) of the test substance was established as 40 mg/kg bw/day in this study, based on elevated absolute kidney weights in mid and high dose females histopathological changes in high dose males, clinical changes in high dose animals, and increased food consumption ad weight gain in mid/high dose males.

TEST FACILITY Bio-Medical Research (1996).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical

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

	Plate incorporation procedure/pre-incubation procedure with S9 in experiment 2.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	Aroclor 1254-induced rat liver post-mitochondrial fraction (S9).
Concentration Range in Main Test	Test 1 a) With metabolic activation: Test 1: 15.81 - 5000 µg/plate b) Without metabolic activation: Test 1: 15.81 - 5000 µg/plate Test 2 a) With metabolic activation: Test 2: 156.25 - 5000 µg/plate b) Without metabolic activation: Test 2: 156.25 - 5000 µg/plate
Vehicle	Purified water.
Remarks - Method	Statement of GLP. No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	No toxicity observed	5000 (TA1537)	None	Negative
Test 2	-	No toxicity observed	None	Negative
Present				
Test 1	No toxicity observed	No toxicity observed	None	Negative
Test 2	-	No toxicity observed	None	Negative

Remarks - Results	The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains, either in the presence or absence of activation in either test. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Covance (2001d).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 88/302/EEC B.10: Other Effects-Mutagenicity: In vitro Mammalian Cytogenetic Test.
Cell Type/Cell Line	Human lymphocytes.
Metabolic Activation System	Aroclor 1254-induced rat liver post-mitochondrial fraction (S9).
Vehicle	dimethylsulfoxide.
Remarks - Method	Statement of GLP. No significant protocol deviations. Doses selected based on precipitation and cytotoxicity observed in preliminary test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 333*, 1000*, 1778*	3 hours	24 hours
	0, 100, 333*, 562, 1000*, 1334*, 1540	24 hours	24 hours

	0, 333*, 1000*, 1334*, 1540, 1778	48 hours	48 hours
Test 2	0, 333*, 562*, 1000*, 1334, 1400	24 hours	24 hours
Present			
Test 1	0, 333*, 1000*, 1778*	3 hours	24 hours
	0, 333, 1000, 1778*	3 hours	48 hours
Test 2	0, 333*, 1000*, 1778*	3 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	*Cytotoxicity in PreliminaryTest**	*Cytotoxicity in Main Test**	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 1778	> 1778	1778	Negative
	1000	1334	>1540	Negative
	1778	1540	1778	Negative
Test 2	1000	1000	>1400	Negative
Present				
Test 1	> 1778	1000	1778	Negative
	-	> 1778	1778	Negative
Test 2	-	> 1778	1778	Negative

*Based on ≥50% decrease in mitotic index

Remarks - Results: No biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION: The test substance was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Notox (1996).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	None specified
Analytical Monitoring	Oxygen Consumption Measuring Apparatus; HPLC
Remarks - Method	Triplicate analyses were prepared of the test substance (100 mg/L), activated sludge (30 mg/L) and basal medium. A control was run using aniline (100 mg/L) and activated sludge (30 mg/L). Two controls were run, one with activated sludge and basal medium and the other being an abiotic control, with test substance (100 mg/L) and basal medium. Temperature 25 ± 1°C. pH 6.5

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	58
14	0	14	58
21	0	21	58
28	0	28	58

Remarks - Results	The results were calculated from Biological Oxygen Demand (BOD). A further calculation was performed using Dissolved Organic Carbon (DOC). The abiotic control showed greater degradation than the test and no degradation was calculated from DOC. A recovery test was performed and showed 98% recovery of the test substance. The aniline reference test was cloudy and showed growth of the sludge. The test substance preparations were red in colour and showed no sludge growth. The reference substance showed 58% degradation after 7 days but was showing 58% degradation after 28 days. Although a valid test requires greater than 65% of aniline to degrade after 14 days, it is unlikely that this anomaly would materially affect the result of 0% degradation for the test substance. The results for the test substance showed negative degradation, but this was recorded as zero.
CONCLUSION	The test substance is not considered readily biodegradable.
TEST FACILITY	Mitsubishi Chemical Safety Institute Ltd. (1995)

8.1.2. Bioaccumulation

The test substance is highly water soluble and is therefore not expected to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	In accordance with OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - static
Species	Rainbow Trout *Oncorhynchus Mykiss*

Exposure Period	96 hrs
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Visual Observation
Remarks – Method	Preliminary solubility tests were conducted and a precipitate was observed in concentrations above 40 mg/L. Consequently the test solutions were limited to less than 40 mg/L. A range finding test was conducted by subjecting 3 fish to single preparations of 3.5 and 35 mg/L of the test substance, including moisture content. A control was also run. A definitive test was then conducted by subjecting duplicate preparations of ten fish to 35 mg/L (including moisture content) of test substance. A stability test was also conducted over a period of 24 hrs at ambient temperature and in light and dark conditions. pH: 7.1 - 7.3 Temperature 14.0 °C Oxygen 9.8 – 10.1 mg O_2/L Photo - period 16 hrs light and 8 hrs darkness.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*			*24 h*	*48 h*	*72 h*	*96 h*
35	38.6*	20	0	0	0	0	0

Average of replicates with measurements taken at 0, 24 and 98 hrs.

LC50	>35.0 ≡ 27.8 active ingredient (a.i.) mg/L* at 96 hours.
NOEC	35 mg/L ≡ 27.8 a.i. mg/L* at 96 hours. *Based on water content of test substance.
Remarks – Results	The pH of the solutions is high, considering that the test substance is the free acid, but this is likely to be due to buffering of the test water. The recovery of the test substance from the stability test was 94%. No mortalities or abnormal behaviour was observed in any of the tests conducted.

CONCLUSION — The test substance is not toxic to rainbow trout to the limits of its water solubility.

TEST FACILITY — Safepharm Laboratories (1995c),

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — Free acid of the notified chemical

METHOD — In accordance with OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	270 mg $CaCO_3$/L
Analytical Monitoring	Visual observation
Remarks - Method	Preliminary solubility tests were conducted and a precipitate was observed in concentrations above 40 mg/L. Consequently the test solutions were limited to less than 40 mg/L. Two range finding tests were conducted by subjecting ten daphnia to single preparations of 3.5, 30 and 35 mg/L of the test substance including moisture content. A control was also run. A definitive test was then conducted by subjecting quadruplicate preparations of ten daphnia to 35 mg/L (including moisture content) of test substance. The control was run in duplicate. A stability test was also conducted over a period of 24 hrs at ambient temperature and in light and

dark conditions.
pH: 7.4 - 7.7
Temperature 21.0 °C
Oxygen 8.0 – 8.4 mg O_2/L
Photo - period 16 hrs light and 8 hrs darkness.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
35	38.4	40	0	0

Average of replicates with measurements taken at 0 and 48 hrs

LC50	> 35 ≡ 27.8 mg/L* a.i. at 48 hours
NOEC	35 ≡ 27.8 mg/L* a.i. mg/L at 48 hours *Based on water content of test substance.
Remarks - Results	The pH of the solutions is high, considering that the test substance is the free acid, but this is likely to be due to buffering of the test water. The recovery of the test substance from the stability test was 88%. No mortalities or abnormal behaviour was observed in any of the test conducted.

CONCLUSION — The test substance is not toxic to rainbow trout to the limits of its water solubility.

TEST FACILITY — Safepharm Laboratories (1995d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — Notified Chemical

METHOD — SOP E203 based on OECD TG 201 Alga, Growth Inhibition Test.

Species	*Scenedemus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 1- 100 mg/L Actual: 9.8 – 97.7 mg/L
Auxiliary Solvent	None
Water Hardness	25 mg $CaCO_3$/L for the culture medium
Analytical Monitoring	Haemocytometer and microscope.
Remarks - Method	Triplicate analyses of approximately 1 × 10^4/mL algal cells were subjected to nominal concentrations of test substance of 10, 18, 32, 56, 100 mg/L. The concentrations were prepared from a stock containing 177mg/L of whole product (≡ 100mg/L pure substance) and culture medium. The notified chemical is coloured and hence was also tested for the light only effect. This was performed in triplicate by subjecting approximately 1 × 10^4/mL algal cells in a nutrient medium to light shielded by (but with no direct contact) nominal concentrations of test substance of 10, 18, 32, 56, 100 mg/L. Six blank studies were also performed in each study. A reference test was also performed using 0, 0.13, 0.25 0.50, 1.0 and 2.0 mg/L of Potassium Dichromate. Temperature 23 ± 2°C. pH 7.1 - 7.3 Illumination 7200 – 9000 lux continuous white light.

RESULTS

Biomass		*Growth*	
<EbC50>	*<EbC50>*	*<ErC50>*	*< ErC50>*

mg/L at 72 h Light Only	*mg/L at 72 h Light & Toxicity*	*mg/L at 72 h Light Only*	*mg/L at 72 h Light & Toxicity*
> 100	30	> 100	> 100

Remarks - Results	The solutions were observed to be coloured and clear. The EbC50 and ErC50 for the reference substance were 0.35 and 0.72 mg/L respectively. Algae was slightly more sensitive to light shielding and toxicity of the notified chemical than to the light shielding effect alone.
CONCLUSION	The notified chemical is harmful to algae resulting from the light and toxicity effects.
TEST FACILITY	Chemex International (2001)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Free acid of the notified chemical
METHOD	In accordance with OECD TG 209 Activated Sludge, Respiration Inhibition Test and EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Sewage sludge micro-organisms from the aeration stage of the Severn Trent Water Plc sewage treatment plant (STP) at Belper, Derbyshire, U.K. treating predominantly domestic sewage.
Exposure Period	3 hours
Concentration Range	Nominal: 1 - 1000 mg/L Actual: 0.79 - 793 mg/L based on correction for moisture content.
Remarks – Method	A range finding test was conducted by subjecting sewage sludge (suspended solids 3.9 g/L) to nominal concentrations of test substance of 1.0, 10, 100, 1000 mg/L (including moisture content). The oxygen consumption of each preparation was measured. A control was run in duplicate as well two reference substance preparations of 3.2 and 32 mg/L of 3, 5 –dichlorophenol. A definitive test was then performed using triplicate preparations of nominally 1000 mg/L of test substance (including moisture content) and 3.2, 10 and 32 mg/L of 3, 5 – dichlorophenol as a reference substance. A control was also run in duplicate. Temperature 21°C Ordinary laboratory lighting.
RESULTS	
IC50	> 1000 ≡ 793 a.i. mg/L
NOEC	1000 ≡ 793 a.i. mg/L
Remarks – Results	The test material did not all dissolve. The variation in respiration of the controls was ± 12%. The inhibition of respiration of sewage sludge was 10 -23%. This was considered to be within the experimental error and hence it was not considered to inhibit the respiration rate. The IC50 of the reference material was 8.0 mg/L
CONCLUSION	The test substance is practically non toxic to sewage sludge micro-organisms to the limits of its water solubility.
TEST FACILITY	Safepharm Laboratories (1995e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority (95%) of the chemical will be used for its intended use as ink on printed paper products. It is expected that the ink containing the notified chemical will remain intimately bound to the paper products. The printed paper products at the end of their useful life will be landfilled, with some being possibly incinerated and approximately 50% of the paper product being recycled in plants throughout Australia. During recycling the paper products will be de-inked. This will result in up to 475 kg of the notified chemical requiring disposal. The inky residue containing the notified chemical may be used as soil conditioner or possibly incinerated. The remainder will be flushed to the sewer. Assuming a worst case scenario where all of the ink is flushed to sewer and none of the ink is adsorbed to sewage sludge in the STP then the predicted environmental concentration (PEC) of the notified chemical at sewage outfall is calculated as 0.45 µg/L. (475 kg ÷ (260 working days × 20.5 × 10^6 persons × 200 L per day)). The actual concentration is likely to be considerably less than the worst case scenario as much of the notified chemical is expected to be disposed in soil conditioner. Any of the chemical adsorbing to sewage sludge is expected to be landfilled or incinerated. During incineration it is expected the notified chemical will be combusted to form oxides of nitrogen, carbon and sulphur; and water vapour, with the metal oxide formed reporting to the ash.

From the Koc values and the chemicals anionic functional groups, it is expected that any notified chemical in soil will only be slightly mobile and will eventually undergo degradation by biotic and abiotic processes. In landfill the notified chemical is expected to slowly degrade within the packaging or on the paper matrix to which it is bound. Any chemical released from the packaging or paper is expected to be only slightly mobile in soils and is expected to continue to degrade.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below.

Organism	Duration	End Point	Toxicity mg/L
Fish	96 h	LC50	> 27.8
Daphnia	48 h	LC50	> 27.8
Algae Biomass	72	EbC50	30
Algae Growth	72	ErC50	> 100

A predicted no effect concentration (PNEC) may be calculated from the highest toxic effect (algae) by a safety factor of 100. The safety factor of 100 is used because toxicity data is available for three trophic levels (fish, daphnia and algae). The resulting PNEC is 0.3 mg/L

9.1.3. Environment – risk characterisation

A worst case risk quotient (RQ) may be calculated by dividing the PEC by the PNEC (0.45µg/L ÷ 300µg/L). The resulting RQ is < 0.01. The worst case scenario demonstrates minimal risk to the aquatic environment. A more realistic release pattern would result in the risk being even lower. Consequently the notified chemical is not expected to pose an unacceptable risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The most likely exposure route for the notified chemical is dermal. Contact may occur if residues of the ink (containing up to 5% notified chemical) are left in the printer or on the cartridge. Exposure would then take place when the cartridge is changed or the copier serviced. Typically spent cartridges will be easily replaced with new ones without any contact with ink.

9.2.2. Public health – exposure assessment

The public may be exposed to the notified chemical following transport accidents involving the breakage of cartridges. Each broken cartridge will release up to 330 ml of ink. The total volume of spilled ink is likely to be small and readily contained for adsorption onto an inert material for mechanical collection, together with broken cartridges, for disposal as land-fill. Any contact is

likely to be dermal and of a minimal and transient nature.

In the course of the use of the cartridges, consumers may make dermal contact with the ink preparation containing the notified chemical (up to 5%)where an attempt is made to repair some mechanical mishap involving the cartridges in the printer. Typically spent cartridges will be easily replaced by new ones without any contact with the ink content. On printed paper the notified chemical will be contained in a cured ink preparation and will be inaccessible to human contact. The potential for exposure of the public to the notified chemical is therefore considered to be low.

9.2.3. Human health – effects assessment

Based on the available data and the assumption that the toxicity of the free acid form is indicative of the toxicity of the notified chemical.

The notified chemical was of low acute oral and dermal toxicity in rats, was not a skin irritant in rabbits but was a slight eye irritant, was not a skin sensitiser and was neither mutagenic in bacteria nor clastogenic in human lymphocytes. The NOEL for a 28-day oral repeat dose toxicity study was 40 mg/kg/day based on subtle treatment related effects observed at higher doses.

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

9.2.4. Occupational health and safety – risk characterisation

The amount of the notified chemical to which a worker may be exposed is low, both because of the low volume involved in a likely contact scenario, and because the concentration of the notified chemical in the ink is < 5%. Based on the limited exposure and low toxicity of the notified chemical especially at the concentration introduced the risk to workers may be considered to be low.

9.2.5. Public health – risk characterisation

Public exposure to the ink preparation is most likely to be dermal and of a minimal and transient nature. The notified chemical is present in the ink preparation at a concentration of up to 5%. Based on the limited exposure and low toxicity of the notified chemical especially at the concentration introduced the risk to public health is assessed as 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*.

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.

Chronic Category 3. Harmful to aquatic life with long lasting effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use

pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- No health hazard classification is required according to the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by wiping with absorbent towel and washing residue with water. Minimise amount entering sewer or

waterways.

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

(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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