File No: LTD/1047

4 December 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

IJR-479(Li)

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd (ABN 66 005 002 951) of 1 Thomas Holt Drive, 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: chemical identity, spectral data, identity of impurities and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No.

NOTIFICATION IN OTHER COUNTRIES
USA (2002), Japan (2002) and UK (2002).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
IJR-479(Li).

MOLECULAR WEIGHT
721.34

SPECTRAL DATA
Ultraviolet/visual (UV/Vis), infrared (IR) and nuclear magnetic resonance (NMR) spectra were generated to confirm the structure of the notified chemical and were provided by the notifier.

METHODS OF DETECTION AND DETERMINATION
UV/Vis, IR and NMR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
One impurity at > 10%.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Eighty, 130 or 330 mL cartridges packed in plastic film and pasteboard transported by ship and then road.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 0.5	< 0.5	< 0.5	< 0.5

USE
The notified chemical will be used as an ink colourant and imported in bubble-jet printer cartridges. The cartridges will be used in commercial high speed printers in print shops and offices. The concentration of notified chemical in inks within the imported cartridges is 1-3%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Unknown.

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in ready to use sealed bubble-jet printer cartridges in pasteboard boxes. No reformulation or repackaging will take place.

5.2. Operation Description
Spent cartridges will be removed from the printer and replaced by print shop or office personnel.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Print shop or office personnel.	> 10000	10 seconds	3 – 6 times/year
Maintenance workers.	> 10000	30/maintenance	1.2 times per year

Exposure Details
As the chemical is contained in a sealed cartridge, exposure is predominantly via the dermal route and is expected to be minimal during normal handling and replacement of printer cartridges by service technicians or printer users. Exposure may occur in the event of a cartridge leak although this is expected to be rare. Inhalation exposure to vapours released during the printing process would be negligible. Overall, the potential exposure would be low due to the low concentration of notified chemical present within the cartridge ink, the small size of the cartridges (up to 330 mL), the fact that the ink is expected to remain in the cartridge until released onto the paper and the fact that the notified chemical would be expected to remain bound to the paper after printing.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No release is anticipated as no manufacture or reformulation of the notified chemical will occur in Australia.

RELEASE OF CHEMICAL FROM USE
Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Ink residues contained in the empty cartridges are expected to be about 5% of the import volume (up to 25 kg per annum) and to

remain within these containers when sent to landfill, although release could occur from deterioration of the cartridge. The total import volume of the notified chemical will ultimately be disposed of in either landfill or be incinerated or recycled with paper.

5.5. Disposal

The total import volume of the notified chemical will ultimately be disposed of in either landfill or be incinerated or recycled with paper.

5.6. Public exposure

The cartridges containing the ink of which the notified chemical is a component will not be sold to the public. Therefore, public exposure would be expected to be limited to rupture of containers during a transport accident or exposure any ink released from landfill.

6. PHYSICAL AND CHEMICAL PROPERTIES

Certain physico-chemical properties were measured for the notified chemical (melting point, boiling point, density, flammability limits and autoignition temperature) and the remainder were measured for the free acid form.

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

Melting Point/Freezing Point Not found.

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Decomposition between 250°C and 350°C without melting.
TEST FACILITY Covance (2001a).

Boiling Point None below 400°C.

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
TEST FACILITY Covance (2001a).

Density 1616 kg/m^3 at 19.9°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY Covance (2001a).

Vapour Pressure < 3.8 x 10^{-19} kPa at 25°C.

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Measured for free acid.
TEST FACILITY Safepharm (1995a).

Water Solubility 277 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Six samples containing excess test substance (10 g) in double distilled water (20 mL) were stirred in closed flasks at 30°C for 24, 48 and 72 hours followed by equilibration at 20°C for a further 24 hours. The solutions were then sampled and centrifuged to remove particulate matter and the solubility was determined by HPLC.
TEST FACILITY Covance (2001a).

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

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

pH	*T (°C)*	*$t_{½}$ (days)*
4	25	220
7	25	> 365
9	25	> 365

Remarks Aliquots (2 mL) of the free acid of the notified chemical in DMSO (~300 mg in 200 mL) were diluted to 200 mL with pH 4, 7, and 9 buffer and were then incubated at 50°C. An addition incubation was also conducted with pH 4 buffer at 40°C. Precautions were taken to minimise photolysis, oxidation and biodegradation. After up to 264 h samples of these solutions were analysed by HPLC. The half-life at each temperature for the pH 4 buffer solutions were determined from graphs of log concentration versus time and use of the Arrhenius relationship.

TEST FACILITY Safepharm (1995a).

Partition Coefficient (n-octanol/water) log Pow at 20ºC = -2.11

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

Remarks The partition coefficient was determined on the free acid of the notified chemical and using the shake flask method described in EC Directive A.8. Based on a preliminary test conducted to determine an approximate partition coefficient, a stock solution of the test material was prepared using n-octanol saturated water. This stock solution was then used to perform three partitions in duplicate involving octanol:water volume ratios of 2:1, 1:1 and 1:2 each shaken for a period of 5 mins. Aliquots of the aqueous and organic phases were taken and analysed by HPLC and the ratio of the concentrations of the free acid in each phase were used to calculate the partition coefficient. The low log Pow indicates a low affinity for the organic component of soils and sediments.

TEST FACILITY Safepharm (1995b).

Adsorption/Desorption
– main test

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

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

Remarks The adsorption/desorption was determined on the free acid of the notified chemical. Samples of the three soil types were dried and ground to a particle size of less than 2 mm prior to use. The test material (~150 mg) was added to DMSO (25 mL) and this solution was further diluted by a factor of 1000 with 0.01M aqueous calcium chloride. To determine the adsorption of the test substance, the test substance solution (20 mL) was added to a sample of each of the three soil types (~500 mg) and the resulting suspensions were shaken for a period of 16 h. After this time the samples were centrifuged to separate the phases and analysis of the aqueous phase (20 mL) was conducted by HPLC. The desorption of the test substance was determined by taking the supernatant removed from the previous step and replaced by adding 0.01M aqueous calcium chloride (20 mL) and shaking in the dark for a period of 16 h. After this time the samples were centrifuged to separate the phases and analysis of the aqueous phase (20 mL) was conducted by HPLC. The desorption step was repeated using a further aliquot of 0.01M aqueous calcium chloride (20 mL). The adsorption coefficient was then calculated from the ratio of the concentration of the test substance in the soil and in the aqueous phase.

The result suggests that the acid form of the notified chemical will be relatively immobile in soil.

TEST FACILITY Safepharm (1995a).

Dissociation Constant

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks The notified chemical is a salt of a weak organic acid and as such is expected to be fully dissociated at high pH.

TEST FACILITY

Particle Size

METHOD

Remarks Test not conducted.

TEST FACILITY

Flash Point

METHOD .

Remarks Test not conducted.

Flammability Limits Not highly flammable.

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

Remarks

TEST FACILITY Covance (2001a).

Autoignition Temperature 291°C

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

TEST FACILITY Covance (2001a).

Explosive Properties No explosive properties.

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

Remarks Measured using the free acid.

TEST FACILITY Safepharm (1995c).

Reactivity

Remarks Not specifically tested except for oxidising properties (see below).

ADDITIONAL TESTS

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 Concentration: 1g/L.

TEST FACILITY Covance (2001a).

Oxidising Properties No oxidising properties.

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

Remarks Measured using the free acid.

TEST FACILITY Safepharm (1995c).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 40 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations in human lymphocytes	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE — IJR-479(Li)

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.

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; less common examples of lethargy, exophthalmos and straub tail resolved by day 7. 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.

At 500 mg/kg bw: discoloured faeces.

Effects in Organs — None.

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

TEST FACILITY — Covance (2001b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE — MJR-580(H) (free acid form 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.

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 notified chemical is of low toxicity via the dermal route.

TEST FACILITY Safepharm (1995d).

7.3. Acute toxicity - inhalation

Data not provided.

7.4. Irritation – skin

TEST SUBSTANCE MJR-580(H)

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Test substance moistened with distilled water.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.

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		0
Oedema	0	0	0	0		0

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

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Safepharm (1995e).

7.5. Irritation - eye

TEST SUBSTANCE MJR-580(H)

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

Species/Strain	Rabbit/New Zealand White.
Number of Animals	3
Observation Period	21 days.

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	72 hours	0
Conjunctiva: chemosis	0	1.33	1.33	2	72 hours	0

Conjunctiva: discharge	0	0.67	0.33	3	24 hours	0
Corneal opacity	0	0.67	4	4	14 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 at 7 days. Corneal opacity was severe in one animal at times up to 72 hours due to staining.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Safepharm (1995f).

7.6. Skin sensitisation

TEST SUBSTANCE: IJR-479(Li)

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

MAIN STUDY

Number of Animals: Test Group: 20 Control Group: 10

INDUCTION PHASE: Induction Concentration:
intradermal injection, 5% w/v
topical application, 50% w/w

Signs of Irritation: Slight erythema at the injection sites; for topical induction no erythema in 6 animals and unable to assess because of staining for the remaining 14 animals.

CHALLENGE PHASE

1st challenge: topical application: 25% w/w
topical application: 50% w/w

2nd challenge: topical application: not done

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: MJR-580(H)

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

	Japanese Guidelines for Screening Toxicity Testing of Chemicals.
Species/Strain	SPF Crj:CD(SD) rats.
Route of Administration	Oral – gavage/diet/drinking water.
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.

RESULTS

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

Clinical Observations

Salivation in some males of the high dose group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry: Elevated inorganic phosphorus in high dose males and calcium in high dose females.

Haematology: No findings.

Urinalysis: No 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.

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: Eosinophilic granules in the proximal tubular epithelium in all male dose groups which resolved during the recovery period. Eosinophilic bodies and lymphocyte infiltration were observed in the mid and low dose groups, respectively and atrophy or regeneration of cortical tubules was seen in a few males of all dose groups.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 40 mg/kg bw/day in this study, based on elevated absolute kidney weights in mid and high dose females.

TEST FACILITY Bio-Medical Research (1996).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE IJR-479(Li)

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	a) With metabolic activation: 15.81 - 5000 µg/plate. b) Without metabolic activation: 15.81 - 5000 µg/plate.
Vehicle	Purified water.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	5000 (TA1537)	-	No
Test 2		-	-	No
Present				
Test 1	-	-	-	No
Test 2		-	-	No

Remarks - Results

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 IJR-479(Li)

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	All cultures below selected for metaphase analysis.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 333, 1000, 1778	3 hours	24 hours
	0, 333, 1000, 1334	24 hours	24 hours
	0, 333, 1000, 1334	48 hours	48 hours
Test 2	0, 333, 562, 1000	24 hours	24 hours
Present			
Test 1	0, 333, 1000, 1778	3 hours	24 hours
	0, 1778	3 hours	48 hours
Test 2	0, 333, 1000, 1778	3 hours	24 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				

Test 1	333	1000	1778	No
Test 2		None		No
Present				
Test 1	1778	562		No
Test 2		1778		No

Remarks - Results

CONCLUSION — The notified chemical 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 form of the notified chemical.

METHOD — OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).

Inoculum — Activated sludge – mixed liquor suspended solid.

Exposure Period — 28 days

Auxiliary Solvent — None

Analytical Monitoring — HPLC

Remarks - Method — The biodegradation of the test substance was determined by the measurement of biochemical oxygen demand for a period of 28 days after the medium was inoculated with activated sludge and stored in the dark at 25ºC. Aniline was used as the standard material.

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
14	0	14	58
28	0	28	58

Remarks - Results — Based on biochemical oxygen demand and residual test substance after 28 days, the results indicated that 0 and 3% of the test substance had degraded, respectively, while 58% of the standard degraded in 28 days.
The 3% degradation of the test substance over the 28 day period can be attributed to loss of the test material during analysis and experimental error. The OECD Test Guidelines (for TG 301 C) state that if the percentage degradation of aniline calculated from the oxygen consumption does not exceed 40 per cent after 7 days and 65 per cent after 14 days, the test is regarded as invalid. Therefore, the results this test should be treated with caution.

CONCLUSION — The test was found to be invalid as the percentage degradation of aniline calculated from the oxygen consumption did not exceed 65 per cent after 14 days. Therefore, no conclusion as to the ready biodegradability of the test substance can be made.

TEST FACILITY — Mitsubishi Chemical (1995).

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical

were not provided for this notification. Given the notified chemical's low import volume, water solubility and dispersed use pattern it is unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

The notifier indicates that lithium ion levels of 1 mg/L reduce the survival of Flathead minnows and Daphnia and that the reproduction of these aquatic species was effected at lower concentrations (0.5 mg Li/L). With respect to the notified chemical, the possibility of some toxic effect due to the counter ion cannot be ruled out as its water solubility is much greater that that of the free acid form and would lead to greater bioavailability of Li. However, the low import volume and proposed diffuse use pattern suggest that the possibility of obtaining toxic levels of Li in the aquatic compartment are unlikely.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Free acid form of the notified chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – 96 h Static Test.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	UV

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*					
Nominal	*Actual*		*3 h*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	< LOQ*	10	0	0	0	0	0	0
35	37.9	10	0	0	0	0	0	0

* Limit of Quantification

LC50	> 27.8 mg/L at 96 hours (As test substance purity equals 79.3%).
NOEC	≥ 27.8 mg/L at 96 hours (As test substance purity equals 79.3%).
Remarks – Results	The results of the definitive study showed that no mortalities were observed in the test vessel with the nominal concentration of 35 mg/L of test substance. Furthermore, no sub-lethal effects were observed in the test. After 96 h, 0% mortality was observed at a measured test concentration of 37.9 mg/L. The value for the measured test substance concentration being greater than that for the nominal concentration can be attributed to experimental error. The 96-hour EC_{50} for the test substance to *Oncorhynchus mykiss* is greater than 27.75 mg/L when the purity of the test substance is taken into account.
CONCLUSION	The ecotoxicity data indicate the notified chemical should be considered at worst as harmful to fish based on the OECD GHS characterisation scheme.
TEST FACILITY	Safepharm (1995g).

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Free acid form of the notified chemical.
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48 h Static Test
Species	*Daphnia magna*
Exposure Period	48 hours

Auxiliary Solvent	None
Water Hardness	270 mg $CaCO_3$/L (approximate theoretical value)
Analytical Monitoring	UV

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	<LOQ	10	0	0
35	38.3	10	0	0

* Limit of Quantification

C50	> 27.8 mg/L at 48 hours (As test substance purity equals 79.3%).
NOEC	≥ 27.8 mg/L at 48 hours (As test substance purity equals 79.3%)
Remarks - Results	The immobilisation tests with *Daphnia* were performed in quadruplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed in any of the test vessels. The 48-hour EC_{50} for the test substance to *Daphnia magna* is greater than 27.8 mg/L when the purity of the test substance is taken into account.

CONCLUSION — The ecotoxicity data indicates the notified chemical should be considered at worst as harmful to aquatic invertebrates based on the OECD GHS characterisation scheme.

TEST FACILITY — Safepharm (1995h).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE — The notified chemical

METHOD — OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range Nominal	0, 10, 18, 32, 56 and 100 mg/L.
Concentration Range Actual	0, 9.8, 17.4, 31.2, 54.8 and 97.7 mg/L.
Auxiliary Solvent	None
Water Hardness	25 mg $CaCO_3$/L
Analytical Monitoring	HPLC

RESULTS

Biomass	*Growth*	*NOEC*
E_bC50 mg/L at 72 h	*E_rC50 mg/L at 72 h*	*mg/L at 72 h*
> 100	30	< 10

Remarks - Results	Algae were exposed to the test substance at the measured concentrations of 0, 9.8, 17.4, 31.2, 54.8 and 97.7 mg/L for 72 h at 23˚C under constant illumination and shaking. No abnormalities were detected in any of the replicate test samples. Both biomass and growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance. The notifier indicates that the algal growth inhibition observed was significantly effected by the light shielding effect of the test substance.

CONCLUSION — The ecotoxicity data indicates the notified chemical should be considered

as harmful to algae based on the OECD GHS characterisation scheme. However, the light shielding effect of the test substance does contribute to the inhibition observed.

TEST FACILITY — Chemex (2001).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Free acid form of the notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Nominal Concentration	1000 mg/L
Remarks – Method	The test substance's capacity to inhibit microbial activity was determined by the measurement of biochemical oxygen demand for a period of 3 h after the medium was inoculated with activated sludge and exposed to light at 21°C. 3,5-dichlorophenol was used as the standard material.
RESULTS	
IC50	> 793 mg/L (As test substance purity equals 79.3%).
Remarks – Results	The results indicated that between 10 and 23% inhibition was observed after 3 h. The notifier indicates that this variation resulted from experimental error due to the insoluble nature of the test material at these high concentrations.
CONCLUSION	The results indicate that the notified chemical is not inhibitory to sludge microorganisms.
TEST FACILITY	Safepharm (1995i).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release

Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Release of the ink containing the notified chemical to the environment is not expected under normal use as the cartridge is designed to prevent leakage. Ink residues contained within the empty cartridges are expected to be about 5% of the import volume and to remain within these containers within landfills, although release could occur from deterioration of the cartridge. If leakage does occur, the ink will be contained and presumably disposed of to landfill. Some waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified chemical. Incineration of waste paper will destroy the chemical with the generation of water vapour and oxides of carbon and sulphur.

In addition to landfill, some of the ink printed on paper will enter the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes are expected to go to trade waste sewers. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill.

Therefore, the total import volume of the notified chemical will ultimately be disposed of to either landfill or be incinerated or recycled with paper.

Fate

In landfill, abiotic or slow biotic processes are expected to be largely responsible for the

degradation of the notified chemical as it is not readily biodegradable. As a consequence of its anionic character, the notified chemical is likely to be immobilised through association with cations on the surface of soil particles and sediments. The substance is not expected to bioaccumulate due to its low import volume, water solubility and dispersed use pattern

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate the notified chemical is harmful to fish, Daphnia and algae. The most sensitive species are fish and Daphnia, where the L(E)C50 is greater than 27.8 mg/L and the NOEC is greater than 27.8 mg/L, and algae where the E_rC50 is 30 mg/L.
A predicted no effect concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, Daphnia, algae). The PNEC is calculated by dividing the L(E)C50 value of the most sensitive species in this case by an assessment safety factor of either 100 (OECD) or 1000 (EU). Using a worst case scenario safety factor of 100, since results for fish, daphnia and algae are available, the PNEC for the notifier polymer is 0.3 mg/L.

The notified chemical should be considered as 'Harmful to Aquatic Life' based on the OECD GHS characterisation scheme. However, given its low import volume, limited release to the aquatic compartment and dispersed use pattern it is unlikely to reach levels considered to be toxic to aquatic organisms.

9.1.3. Environment – risk characterisation

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded printer cartridges at landfill sites. Based on the low import volume, method of packaging and low concentration of the notified chemical in ink, release of the notified chemical to the environment is expected to be very low but widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and very little of the notified chemical will partition to the supernatant water which is released to the sewer.
Due to the above it is difficult to calculate a realistic PEC, but this will clearly be less than the PNEC of 0.3 mg/L.

Based on limited environmental exposure resulting from its very low import volume and dispersed use pattern, the likely risk to the environment is expected to be low.

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 are left in the printer or on the cartridge. Exposure would then take place when the cartridge is changed or the copier serviced.

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.

Members of the public are unlikely to contact the notified chemical as an environmental contaminant. Spent cartridges with unused residues will be disposed of as land-fill. Discarded printed paper will either be recycled or sent as land-fill.

In the course of the use of the cartridges, consumers may make dermal contact with the ink preparation containing the notified chemical where an attempt is made to repair some mechanical mishap involving the cartridges in the printer. This possibility is remote and 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 negligible.

9.2.3. Human health - effects assessment

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 but effects at the higher doses were not considered to be severe based on effects in the kidney in females.

The notified chemical would not be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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 < 3%. Provided proper instruction in the handling of inks, particularly in clean-up procedures in the event of contact, are given to workers via MSDS, labels and instruction manuals, the risk to workers may be considered to be low.

9.2.5. Public health – risk characterisation

From the point of importation to the end use of the ink preparation containing the notified chemical, the ink preparation is either enclosed in a cartridge made for insertion in ink jet printers or is present on printed paper in a cured state. The notified chemical is therefore inaccessible to contact by the public and will remain so unless a cartridge (new or spent) is damaged by some mechanical means such an unlikely transport accident. The possibility of cartridge damage is slight. Any public exposure to the ink preparation that does occur 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 3%. The ink is not classified as hazardous according to the NOHSC criteria and 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 to human health under the NOHSC *Approved Criteria for Classifying Hazardous Substances* but is classified as Category: Acute III under the OECD GHS classification scheme and assigned the hazard statement: Harmful to Aquatic Life.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS for ink 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, 1994a). 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 ink 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, 1994b). 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*. Classification for environmental effects under the OECD GHS classification scheme is Category: Acute III and the hazard statement: Harmful to the Aquatic Environment is assigned.

CONTROL MEASURES

Occupational Health and Safety

- 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 in landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (ie. Collect spilled material in dry state and place in containers for disposal) and the resulting waste disposed of to secure landfill.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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