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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

TKP 50085

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals (ABN: 97 005 061 469)
235 Settlement Road
Thomastown, VIC 3074

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, means of identification, purity and identity and % weight of impurities and adjuvants, 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)
None.

NOTIFICATION IN OTHER COUNTRIES
Canada (DSL), China (IECSC), EU (ELINCS), Japan (ENCS), Korea (ECL).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irgasperse Jet Magenta 3 BL (contains >80% notified chemical)

METHODS OF DETECTION AND DETERMINATION

METHOD	Infra-red, NMR- and mass spectroscopy. Elemental analysis. HPLC.
Remarks	Reference spectra were supplied with the notification.

3. COMPOSITION

DEGREE OF PURITY
>80% as supplied in Irgasperse Jet Magenta 3 BL

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported by sea or air in sealed ink 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
Component of ink-jet printer ink at <10%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
Imported by sea or air in sealed ink cartridges. Transported to end users without repackaging.

5.2. Operation description

The notified chemical is imported as a component of aqueous printer ink contained in a sealed cartridge packaged in cardboard. Approximately 80% of cartridges will be for home and office use, and will contain 10 to 20 mL of ink, and the remaining 20% of cartridges will be used in Wide Format printers, mainly for office use, and will typically contain up to 500 mL of ink.

The cartridges will be transported and stored prior to national distribution where they will be used in office or home printing equipment. The cartridges will be installed/replaced either by office workers, service technicians or consumers.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehouse	5	30 mins/day	40 days/year
Point of sale	50	8 hours/day	100 days/year
Office workers	1000	10 minutes/day	3 days/year
Service technicians	50	45 minutes/day	100 days/year

Exposure Details
Exposure to the notified chemical during the importation, transport and storage of the printer cartridges is not expected except in the unlikely event of an accident where the sealed cartridge and its packaging may be breached.

The cartridges will be distributed to a number of outlets, the cardboard cartons opened and individual boxes stacked on shelves. Possibly 20 – 50 workers may be involved in import, transport, storage and stacking shelves for up to 8 hours per day, 50 – 100 days per year.

Office workers and service technicians may be exposed to the notified chemical when changing printer cartridges with service technicians also potentially exposed during printer maintenance. Approximately 1,000 office workers may change cartridges 2 – 3 times per year, with the change taking 10 minutes each time. Service technicians may visit a site once per year, the service taking 45 minutes.

Dermal and possibly ocular exposure may occur. Inhalation exposure is not expected as the ink is liquid and the printing process is not likely to generate aerosols that escape the printer. The extent of exposure will be limited by the low concentration of notified chemical in the ink (<10%), the small volume of ink released from the cartridge and the intermittent contact with cartridges. Service technicians often wear cotton gloves to further reduce dermal exposure.

Users of the printers may be dermally exposed to the notified chemical during handling of printed paper, however, the notified chemical is bound to the paper matrix and not expected to be readily bioavailable except if the paper or other substrate is handled before the ink has dried.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured or reformulated in Australia. The sealed cartridges will be imported. Thus there will be no environmental exposure associated with this process in Australia. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and spillage during 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 notified chemical as part of the formulation contained in the cartridges will be used in printers. The notified chemical can potentially be released to the environment during the disposal of the spent inkjet cartridges, which are to be disposed of by landfill or incineration. The maximum residue present in the spent cartridge is expected to be 5%.

In the end use process it would be expected that the notified chemical would be bound to the paper which will be landfilled, burned or recycled. Where recycling does not occur the notified chemical will be disposed of to landfill, where it is expected to remain bound to the treated paper. In the event of leaching the environmental effects are expected to be minimal due to the low toxicity and bioaccumulation potential of the notified chemical. Empty cartridges will be disposed of with normal office waste and eventually sent to landfill.

5.5. Disposal

The notified chemical is expected to bind firmly to the paper substrate that would be sent to landfill, burned or recycled. When recycled, the ink will be either oxidized by bleaching or released in effluent to the paper mill wastewater treatment process.

5.6. Public exposure

Consumers may be exposed to the notified chemical when changing printer cartridges. Cartridges would be changed 2 – 3 times per year, with the change taking 10 minutes each time. The cartridge design and replacement instructions are designed to limit exposure.

Members of the public may be exposed to the notified chemical through handling of the printed paper. Assuming 1 g of ink produces 3000 A4 pages of text, each page contains 0.3 mg of ink and <0.03 mg of the notified chemical. Once printed onto paper the notified chemical is bound and unavailable for release. Nevertheless, exposure is possible from accidentally handling printed pages prior to the ink being fully dried or if a non-absorbent substrate is placed in the printer. Exposure is also possible from residues in the printer although the cartridges are designed to minimise these residues.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Red powder

Melting Point Substance decomposes

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Using a DSC apparatus, it was found that decomposition of the sample occurred at around 280-320°C without melting. The boiling point was estimated as 569°C using Meissner's method.
TEST FACILITY	RCC (2004a)

Density 1938 kg/m^3 at 20.1ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Determined using a gas comparison pycnometer.
TEST FACILITY RCC (2004b)

Vapour Pressure Not determined

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Estimated using the Modified Watson Correlation (using the calculated boiling point) to be 3.16×10^{-18} kPa at 25°C.
TEST FACILITY RCC (2004c)

Water Solubility 298 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Based on the results of preliminary test, the flask shaking method was used in the main test. The test was performed by dissolving 18 g of the notified chemical in 25 mL of water. The solutions were shaken at about 30ºC for 24, 48 and 72 h. The flasks were then allowed to equilibrate for another 24 h at 20ºC. The supernatant solutions were centrifuged and filtered. The filtrate was diluted with acetonitrile, water and TFA prior to analysis by HPLC.
TEST FACILITY RCC (2004d)

n-Octanol Solubility 2.2 mg/L

METHOD About 0.4 g/100 mL of notified chemical in octanol was stirred at room temperature for 24 hours. After centrifugation (2900 g, 10 minutes), filtering (0.45 µm) and dilution 1:2 with acetonitrile, the amount of notified chemical in solution was determined using HPLC.
Remarks Pre-test only. Used to determine the partition coefficient.
TEST FACILITY RCC (2004d)

Partition Coefficient (n-octanol/water) log Pow = -5.1 at 20ºC

Remarks Calculated from the water and n-octanol solubility.
TEST FACILITY RCC (2004d)

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)*	*Hydrolysis after 5 days (%)*
4	50	<10
7	50	<10
9	50	<10

Remarks A preliminary test was performed at 50°C at pH 4, 7 and 9. Aliquots of each test solution were analysed using HPLC before incubation, after 2.4 h and after 120 h. The notified chemical was found to be stable and thus a main test was not performed.
TEST FACILITY RCC Ltd (2004e)

Adsorption/Desorption – screening test

Koc = 1 - 6

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

Remarks The adsorption coefficient of the notified chemical on soil was estimated by QSAR methods and a HPLC confirmation method. The Koc was estimated by QSAR using 9 regression equations relating the Koc with water solubility and log Pow for the fully anionic form. The average Koc of the notified chemical was estimated to be 1-6. This range was confirmed by a HPLC experiment using acetanilide as a reference (Koc = 18) where Koc was found to be <18 as it eluted well before the reference.

TEST FACILITY RCC Ltd (2004f)

Dissociation Constant

Not determined.

Remarks The calculation was performed to estimate the dissociation constant of the notified chemical based on the molecular structure. The estimation method for the calculation was not designed for such structures.

All dissociation constants are outside of the measurable pH range and were therefore estimated by Hammett and Taft correlation method. The behaviour of the notified chemical in aqueous solutions is dominated by acidic groups.

The notified chemical will remain dissociated throughout the environmental pH range of 4-9.

TEST FACILITY RCC Ltd (2004g)

Particle Size

MMD < 3.0 µm
Respirable (<10 µm): 83.12

METHOD European Commission Guidance Document ECB/TM/February 1996 Particle Size Distribution, Fibre Length and Diameter distribution.

Range (µm)	*Mass (%)*
<1	16.96
1-3	33.17
3-5	15
5-10	17.99
10-15	9.89
15-20	4.65
20-40	2.26
>40	0.08

Remarks Measured using laser diffraction.

TEST FACILITY RCC (2004h)

Flammability

Not flammable.

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

Remarks The test substance could not be ignited under the test conditions.

TEST FACILITY RCC (2004i)

Autoignition Temperature

247ºC

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

Remarks A well defined exothermic reaction began at about 238°C. A maximum sample temperature of 497.7°C was reached.

TEST FACILITY RCC (2004j)

Explosive Properties Not explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Negative by heat, shock and friction.
TEST FACILITY	ISS (2004)

Oxidizing Properties Not oxidising.

METHOD	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	The reaction of notified chemical/cellulose compared to barium nitrate/cellulose was very slow. The reaction was only observed at the surface, and the test mixture was not burning, only glowing. This is characteristic of non-oxidising substances.
TEST FACILITY	(2004k)

Reactivity Expected to be stable under normal environmental conditions.

Remarks	Thermal decomposition or burning may release oxides of carbon, nitrogen and sulfur. Other toxic gases and/or vapours are also possible in a fire.

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
Mouse, skin sensitisation – LLNA.	no evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic

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/HanBrl:WIST (SPF)
Vehicle	Water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6/F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	Two treated animals showed a loss of body weight (0.6% and 5.9%) between test day 8 and day 15. Slightly ruffled fur was noted in three animals at the 3 and 5-hour reading and persisted up to test day 2. Dark discoloration of the faeces was observed in the cages from test day 2-5.
Effects in Organs	None.
Remarks - Results	None.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC (2004j)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	water
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000 mg/kg	0

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None.

Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	Slight to moderate red discolouration was observed on the treated skin area of most animals from day 2 to day 14.

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

TEST FACILITY RCC (2004k)

7.3. Acute toxicity – inhalation

Not performed.

7.4. 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
Vehicle	Moistened with water prior to application.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	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	1	1 hour	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	Slight erythema was noted in one animal at the 1-hour reading. Slight red staining of the treated skin was observed in all animals from the 1-hour reading up to the 14 days after treatment, the end of the observation period.

CONCLUSION The notified chemical is not irritating to the skin according to the Approved Criteria.

TEST FACILITY RCC (2004l)

7.5. 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
Observation Period	72 hours
Remarks - Method	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	0.33	0.67	1	48 hours	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Corneal opacity	0.33	0	0	1	24 hours	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: Corneal opacity, due to violet staining, and affecting the whole area, was observed in two animals at the 1-hour reading and in one animal 24 hours after treatment. Slight reddening of conjunctivae was noted in all animals at the 1- and 24-hour observation and persisted to 48 hours in two animals. Slight chemosis of conjunctiva was noted in all animals at the 1-hour examination.

A 1% (w/w) solution of the notified chemical was found to have pH 3.88.

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

TEST FACILITY: RCC (2004m)

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

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 429 (Draft): Skin sensitisation: Local Lymph Node Assay
- Species/Strain: Mouse/CBA/CaOlaHsd
- Vehicle: Ethanol/water 7:3
- Remarks - Method: No significant protocol deviations. 10% was the highest technically achievable concentration in the vehicle. The validation test was performed in a different experiment, using the positive control substance alpha-hexylcinnamaldehyde in acetone:oil 4:1.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	335	1
2.5	188	0.6
5	354	1.1
10	303	0.9
Positive Control		
0 (vehicle control)	420	1
5	610	1.5
10	1345	3.2
25	2892	6.9

Remarks - Results: The positive control substance gave results consistent with sensitisation.

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: RCC (2003)

7.7. Repeat dose toxicity

Not performed.

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 (Test 1) Pre incubation procedure (Test 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 33-5000 µg/plate b) Without metabolic activation: 33-5000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	None.	None.	None.
Test 2	5000 µg/plate (TA 98)	None.	None.
Present			
Test 1	None.	None.	None.
Test 2	None.	None.	None.

Remarks - Results	Appropriate substances were used as positive control substances, and these induced a distinct increase in the number of revertant colonies.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC (2004n)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. EU Commission Directive 92/69 EEC, C.4-C
Inoculum	Aerobic activated sludge from a wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC analyser
Remarks - Method	The % biodegradation of the test item was calculated based on a total carbon content (TOC) of 15 mg TOC/L. For the abiotic control and the abiotic control, the untreated test medium was poisoned with mercury dichloride at a concentration of 10 mg/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
2	3.4	2	43.2
5	5.2	5	66.5
7	5.8	7	69.8
14	3.3	14	74.1
19	3.8	19	82.8
23	4.0	23	86.5
28	4.2	28	91.1

Remarks - Results	The percentage biodegradation of the test substance was calculated based on a TOC of 0.292 mg C/mg test item. The CO_2 production of the test item was similar or only slightly above the CO_2 production of the inoculum controls. No significant degradation of the test item occurred in the abiotic control under the test conditions. The validity of the activated sludge was confirmed by the reference substance. Biodegradation in the toxicity control was >25% within 14 days of incubation, indicating that the test item had no inhibitory effect on activated sludge. Temperatures and pH were found to be within acceptable limits.
CONCLUSION	The test item is considered to be not readily biodegradable.
TEST FACILITY	RCC Ltd (2004o)

8.1.2. Bioaccumulation

Based on the logPow of –5.1, it is unlikely that the notified chemical has the potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static Test
Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	221 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		1h	*24h*	*48h*	*72h*	*96h*
100	7	0	0	0	0	0
Control	7	0	0	0	0	0

LC50	>100 mg/L at 96 h (nominal).
NOEC (or LOEC)	100 mg/L at 96 h (nominal).
Remarks – Results	The test media were clear, red-coloured solutions throughout the entire test duration. The test item was stable over the test period. The analytically determined test item concentration in the test medium varied in the range of 99-104% of the nominal values. No mortality or sub-lethal effects were observed at the limit concentration tested. The NOEC was determined directly from the raw data. LC50 could not be quantified due to the absence of a toxic effect of the test substance at the test concentration. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test.
CONCLUSION	The notified chemical is considered to be practically non-toxic to fish.
TEST FACILITY	RCC Ltd (2004p)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static Test EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static Test
Species	*Daphnia magna*
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	No significant protocol deviations.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
Control	20	0	0
4.6	20	0	0
10	20	0	0
22	20	0	0
46	20	0	0
100	20	0	0

LC50	>100 mg/L at 48 h (nominal)
NOEC	100 mg/L at 48 (nominal)
Remarks - Results	The test media were clear, red-coloured solutions throughout the entire test duration. The test item was stable over the test period. The analytically determined test item concentration in the test medium varied in the range of 93-95% of the nominal values. No mortality or sub-lethal effects were observed at the concentrations tested. The NOEC was determined directly from the raw data. LC50 could not be quantified due to the absence of a toxic effect of the test substance at the test concentration. Water quality measurements (pH, dissolved oxygen and temperature) were within acceptable limits throughout the test.
CONCLUSION	The notified chemical is considered to be practically non-toxic to daphnia.
TEST FACILITY	RCC Ltd (2004q)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	Green alga (*Scenedesmus subspicatus*)
Exposure Period	72 h
Concentration Range	Nominal: 1.0, 3.2, 10, 32 and 100 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test consists of two parts in order to separately quantify the algicidal effect and the growth inhibition caused by reduced light intensities from the coloured test solutions. In Part A the algae were grown in test media in the presence or absence of dissolved test item. Nominal concentrations of 1.0, 3.2, 10, 32 and 100 mg/L were used. Each concentration of test item was prepared and tested in triplicate. For the control 6 flasks were prepared. Each flask was placed in a black cylinder. On top of each cylinder were placed glass dishes containing pure water, covered with watch glass. In this way, all of the illumination reaching the algae passed through the glass dishes. In Part B the glass dishes above the cylinders contained the coloured test media with the same test item concentrations as in Part A. In the glass dishes below, the algae grew in the absence of the test item. Thus the growth inhibition in Part B was caused by light absorption only.

All flasks were incubated in a temperature controlled water bath and continuously illuminated by fluorescent tubes. Small volumes of the test media and the control were taken out of all test flasks after 24, 48 and 72 h of exposure. The algal cell densities in the sample were determined by counting and the shape of algal cells were examined microscopically.

RESULTS

Experiment	*Biomass*		*Growth*	
	EbC50	*NOEC*	*ErC50*	*NOEC*
	mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
A	24.8 (CI: 14.8 – 47.3)	3.2	>100	3.2
B	86.7 (CI: 43.7 – 106.4)		43.7 (CI: 11.0 – 107)	

Remarks - Results

The analytically determined test item concentrations in the test media varied in the range of 89-107% of the nominal values. The observed growth inhibition effect of the test substance was caused by the light absorption in the coloured test solutions. However, the differences between experiments A and B were too high to conclude that the algal growth inhibition is a result of the reduction in light intensity. Therefore, the results in experiment A are considered for the toxic effect of the test substance on the algae growth.

pH and temperatures were within acceptable limits throughout the test.

CONCLUSION

The test substance is considered to be harmful to algae.

TEST FACILITY

RCC Ltd (2004r)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Aerobic activated sludge from a wastewater treatment plant
Exposure Period: 3 hours
Concentration Range: Nominal: 6.3 - 100 mg/L
Remarks – Method: Nominal concentrations of the notified chemical at 6.3, 12.5, 25, 50 and 100 mg/L were used in the test. In addition, two controls and three concentrations (5, 16 and 50 mg/L) of the reference item 3,5-dichlorophenol were tested in parallel.

RESULTS

IC50: >100 mg/L
NOEC: 100 mg/L
Remarks – Results: Up to and including the concentration of 100 mg/L, the notified chemical had no significant inhibitory effect (<15%) on the respiration rate of activated sludge after the incubation period of 3 hours. The 3 h EC50 could not be calculated but was determined to be >100 mg/L.

The 3 h EC50 for the reference was within the recommended range of 4-28 mg/L confirming the suitability of the activated sludge.

CONCLUSION

The notified chemical is considered not inhibitory to sewage microorganisms.

TEST FACILITY

RCC Ltd (2004s)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Most of the notified chemical will be bound to paper, with the fate of the notified chemical dictated by paper disposal trends. The three main routes of paper disposal are landfill, incineration and recycling. Recent literature suggests that current paper recycling rates in Australia are 70-92% (Australian Environmental Review, 2001). Consequently, most of the paper containing the notified chemical could be recycled.

Paper recycling is carried out in paper mills, where it is likely that at least primary sedimentation occurs, with some facilities also having biological treatment facilities. Therefore, in these facilities it is expected the notified chemical to partially partition into sludge under the usual waste treatment pH, and eventually be disposed of in landfill with other waste sludge. However, due to the high water solubility, about 50% will stay in the water column. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified chemical contained in sludge or in paper disposed of directly through normal garbage.

Following its use in Australia, it is assumed that 50% of notified chemical will eventually be released into the aquatic environment as a result of the paper recycling process. A calculated worst-case scenario daily PEC in the sewer effluent is 0.34 µg/L. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume of 1 tonne is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer, (3) there is no adsorption or degradation in the sewer prior to release.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of the notified chemical in rural areas and coastal water may approximate 0.34 and 0.034 µg/L, respectively.

Incineration of the waste paper will destroy the notified chemical with the generation of water vapours and oxides of carbon, nitrogen, and sodium, and potentially other gasses or vapours.

Except for paper recycling, the notified chemical is not expected to enter the aquatic environment. The high water solubility of the notified chemical indicates that bioaccumulation is unlikely.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate that the notified chemical is very toxic to algae (*Scenedes-mus subspicatus*), where the acute E_bC50 is 24.8 mg/L.

Organism	*Duration*	*Endpoint*	*Concentration (mg/L)*
Zebra fish (Brachydanio rerio)	96 h	LC50	>100
Waterflea (Daphnia magna)	48 h	EC50	>100
Alga (Scenedes-mus subspicatus)	72 h	EbC50	24.8
		ErC50	>100
Sewage micro-organisms	3 h	EC50	>100

The Predicted No Effect Concentration (PNEC) is 248 µg/L, using a safety factor of 100, and the lowest acceptable acute 72 h E_bC50 for algae of 24.8 mg/L.

9.1.3. Environment – risk characterisation

Location	*PEC (μg/L)*	*PNEC (μg/L)*	*Risk Quotient (RQ)*
Australia-wide STPs (worst case)			
Ocean outfall	0.034	248	1.4×10^{-4}
Inland river	0.34	248	1.4×10^{-3}

Both sets of risk quotients indicate an acceptable risk (RQ<1) for both marine and fresh water organisms.

Given the diffuse and widespread use of the ink product, the concentration of the notified chemical in the aquatic compartment is likely to be low. Furthermore, the low RQ values indicate that there is unlikely to be an environmental risk to the aquatic compartment.

It is expected that any waste generated during use will be disposed of by incineration or to landfill. In landfill the notified chemical contained in sludge or in papers will degrade slowly via biotic or abiotic processes. Therefore, environmental risk from the reported use pattern of the notified chemical is likely to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported in pre-packed sealed cartridges. During transport and storage, workers are unlikely to be exposed to the notified chemical except when cartridges are accidentally breached

Office workers and service technicians may be exposed to the notified chemical through dermal contact while changing spent cartridges, repairing printers or during normal printing processes. Ocular and inhalation exposure are not expected. Service technicians are expected to have the highest occupational exposure.

For all workers, due to the design of the cartridge dermal exposure is likely to occur only occasionally and to small quantities of the notified chemical at a concentration of <10% and as such dermal exposure is expected to be low. In addition, exposure is to be avoided because it would stain the skin and/or smudge the printed page. Exposure will be minimised by the use of disposable gloves by service personnel.

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

In a reasonably worst case situation where a worker's entire palms of the hands are covered with the ink containing 10% notified chemical, exposure would be estimated as follows:

Concentration of notified chemical in ink (mg/cm^3)[a]	*Contact area (cm^2)[b]*	*Thickness of ink layer on skin (cm)[b]*	*Dermal absorption (%)[b]*	*Frequency of occurrence (per day)[c]*	*Exposure to notified chemical (mg/kg bw/day)[d]*
194	420	0.01	10	1	1.16

a) Using 10% notified chemical in the ink and density of 1938 kg/m^3 for the notified chemical and 1000 kg/m^3 for the remainder of the ink.
b) data from European Chemical Bureau Technical Guidance Document on Risk Assessment (European Commission, 2003).
c) no frequency data is available. The occurrence of this scenario once per day is considered to be reasonable worst-case.
d) assuming 70kg body weight

9.2.2. Public health – exposure assessment

Similarly to office workers, the public may be intermittently exposed to the notified chemical when replacing spent cartridges, and during use of printers, however, as it is expected that the public will be using the printer less often than workers, exposure is also expected to be lower. Due to the design of the cartridge dermal exposure is likely to occur only occasionally and to small quantities of the notified chemical at a concentration of <10% and as such dermal exposure is expected to be low. In addition, exposure is to be avoided because it would stain the skin and/or smudge the printed page. Dermal exposure may also occur to ink containing the notified chemical by contact with ink that has not yet dried on printed pages. Exposure to the notified chemical is considered to be limited to the dermal route.

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

9.2.3. Human health – effects assessment

No information on pharmacokinetic properties have been supplied, however the physicochemical data indicate that dermal absorption will be low.

The notified chemical is of low acute oral and dermal toxicity. It was slightly irritating to eyes, with some staining that resolved by 48 hours. The chemical did not cause skin sensitisation at up to 10%. In the skin irritation test, slight erythema was noted in one animal at the 1-hour reading, and slight red staining of the treated skin was observed in all animals from the 1-hour reading up to the 14 days after treatment, the end of the observation period.

The notified chemical was not found to be mutagenic in an Ames test.

No data were submitted on chronic, subchronic, or reproductive effects of the notified chemical.

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

Based on the available data, the notified chemical is not classified as a hazardous substance, and is not expected to cause adverse health effects.

The notified chemical is only introduced into Australia at <10% in inks that are contained inside cartridges. Dermal and ocular exposure is unlikely due to the small amount of ink dispensed from the cartridges, and the staining properties of the dye. Chronic exposure of up to 1.16 mg/kg bw/day may occur, although this is likely to be reduced through the use of PPE such as gloves.

Overall, there is low risk with respect to occupational health and safety.

9.2.5. Public health – risk characterisation

Based on the available data, the notified chemical is not classified as a hazardous substance, and is not expected to cause adverse health effects.

Members of the public may come into intermittent dermal contact with small amounts of notified chemical when changing cartridges or from handling wet ink on printed pages. Given the limited exposure and low hazard of products containing <10% notified chemical, the risk to public health is considered to be low.

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

10.1. Hazard classification

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

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.

According to the GHS, the notified chemical is categorised as Chronic III based on algae toxicity data. The substance is not readily biodegradable.

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 a component of ink-jet printer ink at <10%.

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Wear gloves when servicing printers.

  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 incineration, landfill or recycling.

Emergency procedures

- No special precaution necessary

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
- health and/or environmental data becomes available on potential degradation products

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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