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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

S186260

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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
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Toxikos Pty Ltd (ABN 30 095 051 791)
293 Waverley Road
Malvern East VIC 3145

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
Molecular Formula
Structural Formula
Molecular Weight
Impurities
Additives/Adjuvants
Spectral Data
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
The following notifications are currently underway for this chemical:
USA – PMN
EU – VIIB and VIIA
China – 1 - 10tonnes
Japan – low volume
Switzerland
Canada Schedule 1

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
S186260

CAS NUMBER
Not known

METHODS OF DETECTION AND DETERMINATION

METHOD	IR, NMR, MS, UV/Visible spectrum
Remarks	The notified chemical is a complex reaction product and there are no specific methods relating to its detection and determination. However, diagnostic spectral data are available and the notified chemical may be quantitatively determined by IR, NMR, MS, UV/Visible spectrum spectrophotometry with absorbance detection at appropriate analytical wavelength.

TEST FACILITY Intertek (2005)

3. COMPOSITION

DEGREE OF PURITY
> 80 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported at 5% within a cartridge to be used in inkjet and colour laser printers.

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

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

USE
The notified chemical is a component of ink used in inkjet and colour laser printers at concentration < 5%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
All major ports in Australia

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical is not manufactured nor reformulated in Australia. The printer cartridges containing it will be imported from overseas. The cartridge will be used in printers located throughout Australia.

TRANSPORTATION AND PACKAGING
The notified chemical at concentrations less than 5% will be transported in original cartridge packaging and stored for transport to suppliers. It is imported in closed ink cartridges and stored in boxes for distribution by road transport.

5.2. Operation description
No reformulation or repackaging of the product occurs in Australia. The sealed cartridge is delivered to the end-user in its original packaging. The cartridge will be handled by service technicians and office workers and the public when replacing spent cartridges in the printer.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside workers*	10	4 hours/day	70 day/year
Transport and Warehousing Personnel*	100	6 hours/day	240 days/year
Office workers and Service Technician replacing cartridges	10 000	< 0.1 hours/day	20 days/year

* These workers are not expected to be exposed to the cartridges as they handle closed containers. Only potential for exposure occurs from accident e.g. dropping of container and rupture of cartridges.

Exposure Details
Office workers and service technicians will replace spent ink cartridges. Replacement of printing cartridges involves removal of the old printing cartridge from the printing machine and directly loading the new cartridge. These workers may have dermal contact with very small quantities of the notified chemical if they touch the print heads while replacing cartridges, or on handling printed paper or film, particularly if the paper is handled before the ink is adequately dried or if printing to a non-absorbent substrate occurs by error. After the ink is dry the notified chemical is bound to the paper matrix and is not expected to be readily bioavailable. Inhalation exposure is not expected.

Trained customer service engineers will maintain and clean printing machines and may have similar exposure.

Exposure to dried ink on printed paper would not lead to worker exposure as the ink would be bound, and not available.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The chemical is imported and sold within a printer cartridge, with no reformulation in Australia. No release of the notified chemical will occur except in the unlikely event of spills, where the cartridge is ruptured.

RELEASE OF CHEMICAL FROM USE
During use the notified chemical will be fixed to the paper substrate. At the end of the paper substrate's useful life it will be disposed or recycled. If the paper is recycled it will be de-inked with some of the notified chemical being adsorbed to the sludge and the remainder released to trade waste sewers.

It is expected that up to 5% of the ink containing the notified chemical will remain in the printer cartridge. Most will be disposed as household waste, however approximately 20% is expected to be sent for cartridge recycling. The inks may be incorporated into low grade inks for colouring items such as recycled plastic products. At the end of these products' useful life they will be disposed.

5.5. Disposal
Paper substrates having the notified chemical fixed thereon will be disposed to landfill, incinerated or recycled. During recycling some of the notified chemical will be released to sewer, with the remainder being adsorbed to sludge for disposal by incineration or landfill. Most of the residue in empty cartridges will be disposed to landfill. If the ink is recycled to low grade ink and incorporated into recycled products, then it is likely to be disposed to landfill at the end of the recycled products' useful life.

5.6. Public exposure
The imported cartridges may be transported by air, ship, rail, or truck to their distribution location. The public may be exposed to the notified chemical in the event of an accident during transport involving extensive breakage of cartridges.

The public may also be exposed to the notified chemical during use of printers. The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. The design also prevents leakage of ink. Contact with very small quantities of ink during changing cartridges or on handling incompletely dried printed material may occur. When dry, the ink is expected to be bound to the paper, therefore the exposure to the public would not occur through touching printed paper.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	brown powder

Melting Point/Freezing Point > 300°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Metal block apparatus. The sample was ground before examination.
TEST FACILITY Intertek (2005)

Boiling Point Not available.

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The chemical decomposes without boiling at approximately 340°C
TEST FACILITY Syngenta (2005)

Density 1560 kg/m^3 at 20±0.5°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Using Micromeritics Pycnometer 1330 TC
TEST FACILITY Intertek (2005)

Vapour Pressure <<10^{-6} kPa at 20°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Using Effusion Manometry
TEST FACILITY Syngenta (2005a)

Water Solubility 296-349 g/L at 20°C

METHOD Visual assessment
Remarks As thick pastes formed at ≥ 349 g/L it was not possible to determine the chemical's solubility with any degree of confidence. The chemical was completely soluble at 296 g/L.
TEST FACILITY Intertek (2005)

Hydrolysis as a Function of pH Considered hydrolytically stable.

METHOD Preliminary test. Duplicate tests were conducted on approximately 1g/L of test substance in degassed buffer solutions of pH 4, 7 and 9 at 50 ± 1°C over 5 days. The concentration of the test substance was determined by HPLC.

pH	*T (°C)*	$t_{½}$
4	50	> 5 days
7	50	> 5 days
9	50	> 5 days

Remarks < 10% hydrolysis occurred at pH values of 4, 7 and 9 at 50 ± 1°C over 5 days.
TEST FACILITY Intertek (2005)

Partition Coefficient (n-octanol/water) log Pow = - 3.5

METHOD Shake flask method
Remarks Flask Method
TEST FACILITY Intertek (2005)

Adsorption/Desorption log K_{oc} < 1.5 at 20.9- 22.3°C
– screening test

METHOD OECD TG 121 High Performance Liquid Chromatography (HPLC) Method.
Remarks To ensure that both the ionised and non ionised forms of the chemical were tested, the test was conducted at pH 3 and pH 10. Duplicate analyses were performed using 25 and 50 mg/L of test substance and reference substances at both pH 3 and

pH 10. The retention time for the substance was below the lowest reference substance log Koc value of 1.5 Therefore the substance was assigned a Koc < 1.5.

TEST FACILITY Brixham Environmental Laboratory (2005a)

Dissociation Constant Not available.

Remarks The anionic groups are expected to display typical acidity with pKa of approximately 1.

Particle Size Not Available.

Remarks The notified chemical will be imported only in a liquid form as part of cartridge.

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
EC Directive 92/69/EEC A.13 Pyrophoric properties of solids and liquids.

Remarks The substance did not spontaneously ignite on contact with air at ambient temperature and it is not classified as highly flammable in terms of its pyrophoric properties.

TEST FACILITY Syngenta (2005)

Autoignition Temperature 390±5°C

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

TEST FACILITY Syngenta (2005a)

Explosive Properties Not classified as explosive in terms of its mechanical sensitivity with respect to shock.

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

Remarks Limiting Impact Energy > 40 joules

TEST FACILITY Syngenta (2005a)

Reactivity

Remarks The notified chemical is expected to be stable under normal environmental conditions. An attempt has been made to accelerate, by heating at 54 ± 2 ºC for 14 days, the ageing of Substance S186260. Over the test time period the test substance has been shown to be stable. Therefore, there has not been any significant active ingredient degradation and according to CIPAC MT 46, this indicates an ambient shelf life of at least 2 years. (Intertek 2005)

ADDITIONAL TESTS

Oxidizing Properties Not classified as an oxidising agent

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

Remarks An analogue chemical with similar functional groups and different structure was tested

TEST FACILITY Avecia (2005)

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	no evidence of sensitisation

Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro <Mammalian Chromosome Aberration Test>	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/Sprague-Dawley CD
Vehicle	Distilled water
Remarks - Method	A group of three fasted females was treated with the test substance at a dose level of 2000 mg/kg bodyweight. This was followed by a further group of three fasted females at the same dose level.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0
2	3 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Diarrhoea stained orange and orange stained faeces and urine were noted during the study. There were no other signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	There were no deaths. All showed expected gains in bodyweight over the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2005)

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/ Sprague-Dawley CD
Type of dressing	Semi-occlusive.
Remarks - Method	No significant deviation from protocol. The notified chemical was moistened with water before application.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Very slight to well-defined erythema was noted in eight animals (three males and five females) with haemorrhage of dermal capillaries, glossy skin, hardened light brown-coloured scabs, small superficial scattered scabs and scab lifting to reveal glossy skin were also noted. Some treated skin sites appeared normal five, seven or eight days after treatment.
Signs of Toxicity - Systemic	There were no signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necropsy.

Remarks - Results	There were no deaths. All showed expected gains in bodyweight over the study period except for one female which showed a bodyweight loss during the first week and expected gain in bodyweight during the second week of the study.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	SafePharm Laboratories (2005a)

7.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant deviation from protocol. After 4 h, the residual test material was removed from the skin by gentle swabbing with cotton wool soaked in 74% Industrial Methylated Spirits.

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.

Remarks - Results	Yellow-coloured staining was noted at all treated skin throughout the study. This did not affect evaluation of skin reactions. No evidence of skin irritation was noted during the study.
CONCLUSION	The notified chemical is non-irritating to the skin.
TEST FACILITY	SafePharm Laboratories (2005b)

7.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant deviation from protocol. The eyes of the second and third animals were pre-treated with local anaesthetic.

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	0.3	0.3	0.3	1	24 hours	0
Conjunctiva: chemosis	0.3	0	0	1	24 hours	0

Conjunctiva: discharge	0.3	0	0	1	72 hours	0
Corneal opacity	0	0	0	0	-	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

Orange-coloured staining of the fur was noted around all treated eyes throughout the study.
No corneal or iridial effects were noted during the study.
Minimal to moderate conjunctival irritation was noted in all treated eyes one hour after treatment with minimal conjunctival irritation noted in all treated eyes at the 24-hour observation.
All treated eyes appeared normal after the 48-hour observation.

CONCLUSION

The notified chemical is slightly irritating to the eye.

TEST FACILITY

SafePharm Laboratories (2005c)

7.5. Skin sensitisation

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 406 Skin Sensitisation - <Magnusson-Kligman>.

Species/Strain

Guinea pig/Hartley albino

PRELIMINARY STUDY

Maximum Non-irritating Concentration: 20%
intradermal: 1%, 3%, 5%
topical: 40%, 30%

MAIN STUDY

Number of Animals

Test Group: 20 Control Group: 10

INDUCTION PHASE

Induction Concentration:
intradermal: 5%
topical: 40%

Signs of Irritation

Test animals: Faint to moderate erythema (1-2) was noted at all test sites one hour following patch removal.
Sham control animals: Very faint erythema (0.5) was noted at two sham control sites one hour following patch removal.
Historical positive control animals: Faint to moderate erythema (1-2) was noted at all positive control sites following the topic induction phase.
Historical vehicle control animals: Very faint erythema (0.5) was noted at three vehicle control sites following the topic induction phase.

CHALLENGE PHASE

topical: 20%

Remarks - Method

The scoring system used differed from that in OECD protocol:
0 – no reaction
0.5 – very faint erythema, usually non-confluent, and not considered to be a positive reaction.
1 – faint erythema, usually confluent
2 – moderate erythema
3 – severe erythema, with or without edema
Preliminary sample preparation indicated that mixtures in excess of 40% in distilled water were too dry to ensure adequate contact with the skin.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group			
	20%	10/20	4/20
Control Group			
	20%	4/10	1/10

Remarks - Results	Test animals: Very faint erythema (0.5) was noted at ten of twenty test sites 24 hours following the challenge application. Similar irritation persisted at four sites through 48 hours. Sham control animals: Very faint erythema (0.5) was noted at four of ten sham control sites 24 hours following the challenge. Similar irritation persisted at one site through 48 hours. Historical positive control animals: Nine of ten positive control animals exhibited signs of a sensitisation response (faint to moderate erythema [1-2]) 24 hours after challenge. Similar indications were noted at eight sites through 48 hours. Historical vehicle control animals: Very faint erythema (0.5) was noted for three of five vehicle control sites 24 hours following the challenge. Irritation persisted at one of these sites through 48 hours. Based on the scoring system used in the study, the scores of 0.5 seen in test and control animals on challenge, at a higher incidence in test animals, would not be considered positive responses.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Product Safety Laboratories (2005)

7.6. 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 and Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA (pKM101)
Metabolic Activation System	Unclear from test report which system was used.
Concentration Range in Main Test	a) With metabolic activation: 0, 100, 200, 500, 1000, 2500, 6053 µg/plate b) Without metabolic activation: 0, 100, 200, 500, 1000, 2500, 6053 µg/plate
Vehicle	DMSO
Remarks - Method	No significant deviation from protocol. It is unclear from the test report which metabolic activation system was used. Both Phenobarbital / β-naphthoflavone and Aroclor 1254 induced rat liver fractions are mentioned, in different sections of the report. S186260 was initially assayed using the standard plate incorporation protocol over a dose range of 6053 to 100 µg/plate, both in the presence and absence of S9-mix prepared from Phenobarbital / β-naphthoflavone-induced Sprague-Dawley (SD) rats. S186260 was subsequently re-tested over the same dose range: the +S9-mix phase of this repeat assay was conducted using a pre-incubation protocol. S186260 was subsequently tested using strain TA1537 +S9-mix only, again over the same dose range using the plate incorporation protocol. The incubation period for each experiment was 3 days.

RESULTS

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

Test 1	> 6053 µg/plate	> 6053 µg/plate	none noted	negative
Present				
Test 1	> 6053 µg/plate	> 6053 µg/plate	none noted	negative
Test 2		> 6053 µg/plate	none noted	negative

Remarks - Results

In at least two experiments with each tester strain, the test substance did not induce any significant, reproducible increase in the observed numbers of revertant colonies with any of the tester strains in the presence or absence of S9-mix. Although a slight increase was observed with strain TA1537+S9-mix in the initial plate incorporation experiment, this was not dose-related and was not reproduced in either the pre-incubation experiment or in a further plate incorporation experiment.
The positive controls for each experiment induced the expected responses, indicating the strains were responding satisfactorily in each case.

CONCLUSION

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

TEST FACILITY

Central Toxicology Laboratory (2005a)

7.7. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

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

Cell Type/Cell Line: Human lymphocytes
Metabolic Activation System: S9 fraction from Aroclor 1254 induced rat liver
Vehicle: Water
Remarks - Method: No significant deviation from protocol

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5000*, 2000*, 1000*	3 hours	20 hours
Test 2	1000*, 500*, 250*	20 hours	20 hours
Present			
Test 1	5000*, 2000*, 1000*	3 hours	20 hours
Test 2	5000*, 2500*, 1000*	3 hours	20 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5000 µg/mL	> 5000 µg/mL	negative
Test 2	> 250 µg/mL	> 1000 µg/mL	negative
Present			
Test 1	> 5000 µg/mL	> 5000 µg/mL	negative
Test 2	> 1000 µg/mL	> 5000 µg/mL	negative

Remarks - Results

No statistically or biologically significant increases in the percentage pf aberrant cells, compared to the solvent control values, were recorded in cultures from either experiment treated in either experiment treated in either the presence or absence of S9-mix. Higher levels of aberrant cells were noted in Test 1 at 1000 µg/mL without of metabolic activation and at 5000 µg/mL with metabolic activation, however these were not

statistically significant.
The sensitivity of the test system, and the metabolic activity of the S9-mix employed, were clearly demonstrated by the increase in the percentage of aberrant cells induced by the positive control agents, mitomycin C and cyclophosphamide.

CONCLUSION — The notified chemical was not clastogenic to cultured human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY — Central Toxicology Laboratory (2005)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE — Notified Chemical

METHOD — OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.

Inoculum — Activated Sludge from Buckland Sewage Treatment Works, Newton Abbot, Devon, UK, treating predominantly domestic sewage.

Exposure Period — 28 Days

Auxiliary Solvent — Nil

Analytical Monitoring — Manometer, HPLC

Remarks - Method — Triplicate analyses were performed by adding 100 mg/L of test substance to activated sludge. Six control blanks containing activated sludge but no test substance were run. Triplicate analyses of sodium benzoate as a reference substance were run. In order to account for mechanisms such as adsorption or physical degradation, triplicate analyses were run using the test substance and sludge organisms, which were killed using $HgCl_2$. To ensure that the sample preparation was valid, two 100 mg/L samples of test substance were each used to fortify a test medium and deionised water. The CO_2 produced was absorbed by KOH and the decrease in oxygen pressure was read directly from the manometer.
pH: 7.0 ±1.0

RESULTS

Test substance				*<Reference Substance>*	
Day	*% Degradation*			*Day*	*% Degradation*
5	< 5	< 5	10	5	64
9	< 5	< 5	10	9	68
15	< 5	< 5	10	15	70
20	< 5	< 5	10	20	70
28	< 5	< 5	5	28	69

Remarks - Results — The average concentration of the test substance at 28 days for the analyses where the activated sludge was killed by $HgCl_2$ was 97 mg/L. The recoveries of the samples from the fortified test medium and deionised water were 95% and 96% respectively. No adjustment was deemed necessary. HPLC analysis of the test substance showed no structural change had occurred during the course of the study

CONCLUSION — Not Readily Biodegradable.

TEST FACILITY — Brixham Environmental Laboratory (2005b)

8.1.2. Bioaccumulation

Not Tested. The notified chemical is water soluble with low Koc and is therefore unlikely to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static, gentle aeration.
Species	
Exposure Period	96 hours
Auxiliary Solvent	Nil
Water Hardness	46.3 mg $CaCO_3$/L
Analytical Monitoring	Observation of mortality at 3, 24, 48, 72, 96 hours.
Remarks – Method	A preliminary test was conducted by subjecting seven fish to nominal concentrations of 100, 180, 320, 560, 1000 mg/L of test substance. A blank was also run. Weight (fish) 0.81 – 1.65 g; mean 1.21 g Length (fish) 41 – 52 mm; mean 45 mm Temperature 15 ± 1°C Percentage Dissolved Oxygen 95 – 98 % of saturation. pH: 7.6 – 7.8 Conductivity of dilution water 221 µS/cm Cl_2 in dilution water < 2 µg/L Ammonia as NH_3 in dilution water 14.0 µg/L

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual* [a]		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	< 3.4	7	0	0	0	0	0
100	100	7	0	0	0	0	0
180	180	7	0	0	0	0	0
320	320	7	0	0	0	0	0
560	550	7	0	0	0	0	0
1000	1000	7	0	0	1	5	7

[a] Arithmetic mean of 0 and 96 hour results from triplicate analyses quoted to two significant figures

LC50	> 1000 mg/L at 48 hours. 550 – 1000 mg/L at 96 hours.
NOEC (or LOEC)	560 mg/L at 96 hours.
Remarks – Results	The intense colouration of the test solutions prevented the observations of abnormal behaviour of the fish during the study.
CONCLUSION	Practically non- toxic to fish
TEST FACILITY	Brixham Environmental Laboratory (2005c)

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.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil

Water Hardness	198 mg $CaCO_3$/L of dilution water
Analytical Monitoring	Observation of immobilisation and abnormal behaviour at 24 and 48 hours; HPLC for test substance
Remarks - Method	A preliminary test using five daphnia exposed to 120 mg/L of test substance and a blank were run. The photoperiod was 16 hours light and 8 hours dark with 20 minute transition time. Temperature 20 ± 1°C. pH 8.2 – 8.3 Dissolved Oxygen 8.8 – 9.2 mg/L

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual* [a]		*24 h [acute]*	*48 h [acute]*
0	< 3.4	5	0	0
120	120	5	0	0

[a] Arithmetic mean of 0 and 48 hour results from triplicate analyses quoted to two significant figures

LC50	> 120 mg/L at 24 hours > 120 mg/L at 48 hours
NOEC (or LOEC)	120 mg/L at 48 hours
Remarks - Results	No toxicity was observed in this study. Potassium dichromate was run as a reference toxicant in May 2005. The EC50 was 1.2 mg/L.
CONCLUSION	Practically non- toxic to daphnia
TEST FACILITY	Brixham Environmental Laboratory (2005d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Selenastrum capricornutum
Exposure Period	72 hours
Concentration Range	Nominal: 1.0 - 120 mg/L Actual: 1.0 - 130 mg/L
Auxiliary Solvent	Nil
Water Hardness	Not Specified
Analytical Monitoring	Electronic Particle Count. HPLC
Remarks - Method	Four replicate cultures of nominal cell density of 1×10^4 per mL and mean measured cell density of 1.04×10^4 per mL with 1.0, 2.3, 5.0, 11, 25, 55 and 120 mg/L of test substance were prepared. Two of the replicates were exposed to light and had the test substance in direct contact with the algae. The other two replicates were shaded by the test substance but were not in direct contact with the substance. A control was also run. pH 7.3 – 7.9 Temperature 24 ± 2°C Light Intensity 3970 lux

RESULTS

Nominal Concentration mg/L	Actual[a] Concentration mg/L	Mean area under growth curve	Mean growth rate (0 – 72 hr)	Shaded/ Exposed

	(Mean of 0 & 72 hr)	(0 – 72 hr)		
Control	< 0.44	50.0	1.39	Exposed
1.0	1.0	41.7	1.32	Exposed
2.3	2.5	32.8	1.24	Exposed
5.0	5.7	30.0	1.20	Exposed
11	12	25.2	1.13	Exposed
25	27	18.6	0.996	Exposed
55	61	14.4	0.896	Exposed
120	130	10.6	0.788	Exposed
Control	< 0.44	50.0	1.39	Shaded
1.0	1.0	37.3	1.29	Shaded
2.3	2.5	40.3	1.31	Shaded
5.0	5.7	32.7	1.23	Shaded
11	12	22.9	1.09	Shaded
25	27	16.0	0.95	Shaded
55	61	13.3	0.844	Shaded
120	130	11.4	0.786	Shaded

[a] Arithmetic mean of 0 and 72 hour results quoted to nearest integer significant figures

Biomass		*Growth*	
EbC50 Shaded mg/L at 96 h	*EbC50 Exposed mg/L at 96 h*	*ErC50 Shaded mg/L at 96 h*	*ErC50 Shaded mg/L at 96 h*
11	9.6	> 120	> 120
NOEC Shaded mg/L at 96 h	*NOEC Exposed mg/L at 96 h*	*NOEC Shaded mg/L at 96 h*	*NOEC Shaded mg/L at 96 h*
2.3	2.3	2.3	2.3

Remarks - Results: The inhibition curves of the shaded (S) versus exposed (E) are essentially the same with S/E ≥ 0.9 and the highest test concentration showing that the shaded replicates' inhibition was higher than the corresponding exposed replicates' inhibition. Potassium dichromate was run as a reference toxicant in October 2004. The EbC50 was 0.42 mg/L and the ErC50 was 1.03 mg/L.

CONCLUSION: The effects on algal growth are due to shading. Consequently the notified chemical meets the exemption criteria for coloured substances. (Directive 93/21/EEC)

TEST FACILITY: Brixham Environmental Laboratory (2005e)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Respiration Inhibition Test

Inoculum: Activated Sludge from Buckland Sewage Treatment Works, Newton Abbot, Devon, UK, treating predominantly domestic sewage.

Exposure Period: 3 hours

Concentration Range: Nominal: 1.0 - 100 mg/L

Remarks – Method: Test solutions containing 1.0, 3.2, 10, 32 and 100 mg/L of test substance were inoculated with sewage sludge. Controls containing the same concentrations of dichlorophenol and sewage sludge were run along with an abiotic flask containing 100 mg/L of dichlorophenol but no inoculum. Temperature 20 ± 2°C

RESULTS

IC50: > 100 mg/L

NOEC: 100 mg/L

Remarks – Results	All test concentrations dosed with the notified chemical showed less than 10% inhibition.
CONCLUSION	Practically non – inhibitory to microbial activity.
TEST FACILITY	Brixham Environmental Laboratory (2005f)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical as a component of ink is expected to remain fixed to the paper for its useful life. Assuming that 5% of the chemical will remain in empty cartridges with 95% used for its intended purpose as ink, and with 50% of paper (Nolan ITU) being recycled then up to 425 kg will be disposed during paper recycling. This equates to 1.16 kg per day. This is likely to occur at recycling plants throughout Australia. Assuming a worst case scenario where none of the chemical adsorbs to sludge then a Predicted Environmental Concentration (PEC) is calculated as 0.284 µg/L. This assumes that 20.5 million persons consume 200 L per day of water. The remainder of the paper products will be landfilled or incinerated. Residual chemical in the empty cartridges will be landfilled or recycled, with any recycled product likely to also be landfilled and the end of its useful life. The notified chemical during incineration is expected to be combusted to oxides of sulphur, nitrogen and carbon; and water vapour. In landfill the notified chemical is likely to be mobile based on its Koc value, once the paper substrate or cartridge has degraded. It is expected to eventually degrade by biotic and abiotic processes.

9.1.2. Environment – effects assessment

The lowest toxic end point established was 750 mg/L. Although algae showed an EbC50 of 9.6 mg/L, this was likely to be solely due to physical screening of light. A summary of the valid toxicity data is listed below:

Organism	Duration (hours)	End Point	Toxicity mg/L
Fish	96	LC50	550 - 1000
Daphnia	48	LC50	> 120
Micro-organisms	3	IC50	> 100

A Predicted No Effect Concentration (PNEC) is calculated as > 5500 µg/L using the LC50 for fish and a safety factor of 100 as tests were performed on three trophic levels.

9.1.3. Environment – risk characterisation

The risk quotient for sewage outfall can be derived by dividing the PEC by the PNEC, resulting in a value of < 0.01. Although some of the notified chemical will be released from landfill into waterways, due the chemical's low ecotoxicity, it is unlikely to pose a risk to the aquatic environment. 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

Office workers and customer service engineers may be intermittently exposed to the notified chemical contained in the ink cartridge when replacing the spent ink cartridge, and during repair maintenance and cleaning of ink jet printers. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Customer service engineers may potentially come in contact with the notified chemical more often than office workers. However, customer service engineers often wear cotton disposable gloves. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

Accidental exposure may occur upon handling printed matter where the ink has not dried, such exposure would be minimized by the small amount of printing ink used per sheet of paper and the low concentration of the notified chemical in the ink. The notified chemical would not be separately available for exposure or dermal uptake after drying as it is fused and fixed to the

printed surface.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

9.2.2. Public health – exposure assessment

The printing ink will be available for use in home printers. The public may have dermal exposure to the notified chemical in the printing ink when inserting or removing a damaged cartridge and clearing paper jams. The ink is contained in the cartridge and the physical design of the cartridge minimises dermal exposure. The cartridge design also prevents leakage of ink.

Public exposure could also occur by dermal contact with printed media treated with ink containing < 5% notified chemical. However is most cases the ink would be dry and the notified chemical would be bound to the paper and not bioavailable.

9.2.3. Human health – effects assessment

Toxicokinetics
No information was supplied on the absorption, distribution or excretion of the notified chemical from the human body. However the high water solubility and low participation coefficient suggest that it would not absorbed dermally.

Acute toxicity
The notified chemical is of low acute toxicity via the oral and dermal route.

Irritation
Based on the studies provided in rabbits the notified chemical is considered to be non-irritating to the skin and slightly irritating to the eyes.

Sensitisation
There was no evidence of sensitisation potential to the notified chemical in the guinea pig Magnusson-Kligman test. Therefore, the notified chemical is considered not to be a potential skin sensitiser.

Genotoxicity
The notified chemical tested was not mutagenic to bacterial cells in a reverse mutation study with and without metabolic activation, not clastogenic to cultured human lymphocytes treated in vitro.

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 available test results, the notified chemical is of low oral and dermal toxicity. It is non-irritating to skin and slightly irritating to eyes. It was negative in a reverse mutation study in bacteria and an in-vitro chromosome aberration study. The physico-chemical characteristics of the chemical suggest that it would not be absorbed through the skin.

Dermal exposure of office workers and technicians to the ink containing the notified chemical at < 5% may occur inadvertently while changing cartridges or handling printed paper where the ink has not dried. Contact with printed paper after drying is not expected to lead to exposure.

Based on the low hazard of the chemical, and the low expected exposure, the risk to workers from the notified chemical as a printing ink component is considered low.

9.2.5. Public health – risk characterisation

Given that the manner of exposure for the public is similar to that for office workers performing the same tasks, the risk from public exposure to the notified chemical 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*.

No GHS classification for human health or the aquatic environment is appropriate.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of 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
CONTROL MEASURES
Occupational Health and Safety

No special precautions are required for the notified chemical when used at low quantities as a component of ink cartridges for printers. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed for use of printing inks containing the notified chemical:

- Avoid contact with skin.
- Printers should be located in well-ventilated areas.
- Service personnel should wear cotton or disposable gloves when replenishing spent ink cartridges and 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 authorised landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, preventing entry to drains, sewers and water courses. Collect using an inert absorbent material (vermiculite sand etc.). Rinse area with water preventing entry to drains, sewers and water courses and collect using an inert absorbent material.

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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