File No: LTD/1045

8 October 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

TN-105

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ricoh Australia Pty Ltd (ABN 30 000 593 171) of 8 Rodborough Road, Frenchs Forrest, NSW 2086 and Lanier Australia Ltd (ABN 39 001 568 958) of 854 Lorimer Street, Port Melbourne, VIC 3207.

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formula, molecular weight, spectral data, purity, 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)
None.

NOTIFICATION IN OTHER COUNTRIES
USA & Korea.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
TN-105;
Ricoh Toner type 3105D (containing the notified chemical);
Lanier Toner for 5635/5645 (containing the notified chemical).

3. COMPOSITION

DEGREE OF PURITY
High.

4. INTRODUCTION AND USE INFORMATION

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

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

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

USE
TN-105 is used as a charge control agent in the photocopier toners.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
NSW & VIC.

IDENTITY OF MANUFACTURER/RECIPIENTS
Ricoh Australia Pty Ltd and Lanier Australia Ltd.

TRANSPORTATION AND PACKAGING
The notified chemical is a component of photocopy toners. The ready-to-use cartridge containing <5g notified chemical is sealed and packed in cardboard cartons (6 cartridge per carton). The cartons will be transported from the dockside to the notifiers' warehouse, where they will be stored until distribution to customer outlets around Australia.

5.2. Operation Description

Replacement of photocopier cartridges involved removal of the old cartridge and directly loading the new cartridge into the photocopier. The old one will be put in the cartons and disposal to landfill.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport & storage	8-10	2-3 h/day	10-15 d/year
Customer service engineers	200	5-20 min/day	100 d/year

Exposure Details
Transport and warehouse workers would only be exposed to the notified chemical if the package is breached.

Trained customer service engineers will maintain the photocopiers and change the toner cartridges. They wear cotton gloves if the maintenance procedure involves direct contact with the toner.

After photocopying, the notified chemical is bound to paper. Any dermal exposure to it will be negligible.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The toner products will be imported in sealed cartridges and there will be no release to the environment due to reformulation or repackaging.

RELEASE OF CHEMICAL FROM USE
The toner cartridges will not be opened during transport, use, installation or replacement. Therefore, release of toner containing the notified chemical to the environment is not expected under normal use. The sealed cartridges are contained within the photocopier until they are removed for disposal. Environmental exposure will result from the disposal of printed paper, discarded cartridges and any accidental leakage of the cartridges during use.

About 10% of the toner product is expected to remain unspent. Based on a maximum import volume of 1 tonne, up to 100 kg of the notified chemical will be sent to landfill as residue in empty toner cartridges. Assuming that 75% of paper containing the bound chemical is sent to landfill, approximately 680 kg (68% of the maximum imported volume) of the chemical would be sent to landfill.

The remaining 22% of the notified chemical (approximately 220 kg) bound to paper is expected to enter the paper recycling process. All of the developer containing the notified chemical will be removed from the paper/pulp during the deinking stage of the recycling process. The resulting alkali mixture is likely to be recycled or neutralised and disposed of to a liquid waste facility by a licensed waste contractor.

5.5. Disposal

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

5.6. Public exposure

The toners are only used for commercial purposes hence public exposure is not expected. Once printed onto paper, the notified chemical is bound and unavailable for release.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa White powder.

Melting Point/Freezing Point Decomposed at temperatures above 250°C.

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	GLP & QA.
TEST FACILITY	Huntingdon Life Sciences Ltd (2000a).

Density 1 250 kg/m^3 at 22ºC

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	GLP & QA.
TEST FACILITY	Huntingdon Life Sciences Ltd (2001a).

Vapour Pressure 3.95x10-7 kPa at 25ºC

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	GLP & QA. A vapour pressure test was conducted using a vapour pressure balance. A series of three runs were performed between 26ºC and 69ºC. The results indicate that the notified chemical is classified as being slightly volatile.
TEST FACILITY	Huntingdon Life Sciences Ltd (2000b).

Water Solubility Less than 5 mg/L

METHOD	OECD TG 105 /EC Directive 92/69/EEC A.6 Water Solubility
Remarks	Following a preliminary test showing a water solubility of less than 10 mg/L, a definitive test was performed by the flask method, given the anticipated restrictions of solubility in volatile solvents and coating of supporting material. Wheaton vials containing 10-20 mg of the test substance and 50 mL of purified water were purged with nitrogen, sealed and mixed at 30^{oC} for 1-3 days. These samples were then filtered and a subsample of each filtrate was analysed for its zirconium content. In the absence of suitable substance-specific method of analysis, inductively-coupled plasma spectrometry (ICPS) was employed to determine the total dissolved Zirconium content of the water solubility samples. In addition, specific analysis for the ligand 3,5-di-tert-butylsalicylic acid (3,5-DTBS) served to give an indication of the stability of the complex over the duration of the test. The concentration remaining in the filtrate was determined using high performance liquid chromatography (HPLC). The water solubility of the test substance was less than 5 mg/L.
TEST FACILITY	Huntingdon Life Sciences Ltd (2000a)

Hydrolysis as a Function of pH Not determined.

Remarks Hydrolysis analysis was not practical due to the low solubility of the test substance (less than 10 mg/L). However, the test substance does not contain any groups that would undergo hydrolysis.

Partition Coefficient (n-octanol/water) Not determined.

Remarks Experimental determination of the partition coefficient was not possible. Preliminary solubility checks in n-octanol and water conducted by stirring 10 mg of TN-105 with 1000 mL of each solvent for 4 days, demonstrated a solubility of less than 10 mg/L in both cases as undissolved test substance was clearly visible. The flask method therefore, could not be used. Neither the HPLC method nor providing a calculated value based on the chemical structure was feasible, as neither approach is applicable to metal complexes.
The low water solubility and the estimated high adsorption coefficient of the test substance may indicate a high affinity for the organic component of soils and sediment.
TEST FACILITY Huntingdon Life Sciences Ltd (2000a).

Adsorption/Desorption $Log_{10}K_{oc} > 3.3$

Remarks Based on the water solubility < 5 mg/L, an estimate of K_{oc} was calculated using the relationship:
$Log_{10}K_{oc} = -0.55\ Log_{10}S + 3.64$
The high estimated log K_{oc} is consistent with the low water solubility, indicating a high affinity for the organic component of soil and sediments. The regression equation used to estimate log K_{oc} represents a wide variety of chemical classes. However, as the chemical is a metal complex, this value should be treated with caution.
TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

Dissociation Constant Not determined.

Remarks The dissociation constant was not available, but the complex is expected to remain dissociated except at high pH.

Particle Size 34% by mass is smaller then 10 μm.

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

Range (μm)	*Mass (%)*
>125	3.9
>105	0
60-105	1.6
30-60	13.1
10.4-30	47.7
0.5-10.4	33.7

Remarks GLP & QA.
TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

Flash Point Not determined.

Remarks Not applicable for solids.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks GLP & QA.
TEST FACILITY Huntingdon Life Sciences Ltd (1999a).

Autoignition Temperature 261ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks GLP & QA.
TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks GLP & QA.
TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

Reactivity No hazardous reactions are known if used for its intended purposes.

Remarks No study report was provided.

Surface Tension 72.0 mN/m at 20ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.

Remarks The surface tension of a 90% saturated aqueous solution was determined with a tension torsion balance using the OECD harmonised ring method. Wheaton vials containing 15 mg of the test substance and 100 mL of purified water were shaken at 30ºC in a water bath for 24 hours. The sample was re-equilibrated at 20ºC for a further 24 hours and filtered. The test solution was prepared by diluting 45 mL of filtrate to 50 mL with purified water. Measurements were made at 10 minute intervals until a constant value was recorded (within 0.5 mN/m).

The results indicate that the test substance is not surface active.

TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

Oxidizing Properties TN-105 is non-oxidising.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks GLP & QA.
TEST FACILITY Huntingdon Life Sciences Ltd (2001a).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2 000 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.
Rat, oral-gavage repeat dose toxicity - 28 days.	NOAEL = 15 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE TN-105

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain Rat/Sprague-Dawley (CD)
Vehicle 1% aqueous methylcellulose
Remarks - Method GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2 000	0

LD50	> 2 000 mg/kg bw
Signs of Toxicity	Piloerection, hunched posture, waddling/unsteady gait, abnormal faeces and ungroomed appearance were seen in all rats. The recovery was completed in all instances by day 8.
Effects in Organs	None.
Remarks - Results	None.

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

TEST FACILITY Huntingdon Life Sciences Ltd (1999b).

7.2. Irritation – skin

TEST SUBSTANCE TN-105

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	TN-105 was moistened with 0.5 mL distilled water.
Observation Period	4 days
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

RESULTS The Draize scores of erythema and oedema were zero for all three animals at day 1, 2, 3 and 4.

Remarks - Results No signs of toxicity or ill health in any rabbit were seen during the observation period.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Huntingdon Life Sciences Ltd (1999c).

7.3. Irritation - eye

TEST SUBSTANCE TN-105

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	GLP & QA.

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	0.7	0.3	2	24 h	
Conjunctiva: chemosis	0	0	0	0		0

Conjunctiva: discharge				Not scored.	
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: No signs of toxicity or ill health in any rabbit were seen during the observation period.

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

TEST FACILITY: Huntingdon Life Sciences Ltd (1999d).

7.4. Skin sensitisation

TEST SUBSTANCE: TN-105

METHOD: OECD TG 406 Skin Sensitisation – Magnusson & Kligman.
EC Directive 96/54/EC B.6 Skin Sensitization - Magnusson & Kligman.

Species/Strain: Guinea pig/Dunkin/Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 2.5% in Alembicol D (a coconut oil product).
topical: 60% in Alembicol D.

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

INDUCTION PHASE: Induction Concentration:
intradermal injection 2.5% in Alembicol D.
topical application 60% in Alembicol D.

Signs of Irritation: Slight to well-defined irritation was seen in test animals at intradermal injection sites. Slight irritation was observed in control animals.

Slight to well-defined erythema was observed in both test and control animals following topical application.

CHALLENGE PHASE

1st challenge: topical application: 60% in Alembicol D.
topical application: 30% in Alembicol D.

2nd challenge: topical application: 40% in Alembicol D.
topical application: 20% in Alembicol D.

Remarks - Method: GLP & QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*				
		1st challenge			*2nd challenge*	
		24 h	*48 h*	*72 h*	*24 h*	*48 h*
Test Group	60%	10/10	10/10	9/9		
	30%	0/10	0/10	0/9		
	40%				0/9	0/9
	20%				0/9	0/9
Control Group	60%	5/5	5/5	5/5		
	30%	0/5	0/5	0/5		
	40%				0/5	0/5
	20%				0/5	0/5

Remarks - Results: One test animal was sacrificed following the first challenge due to ulceration around the injection site. No signs of ill health or toxicity were observed for the remaining animals.

During the first challenge, at 60% the sample stuck to the skin causing mechanical damage at bandage removal for all test and control animals.

	No mechanical damage occurred during the second challenge. Since the same test animals were used for the second challenge and negative responses were observed after the second challenge, TN-105 is not considered to be a skin sensitiser.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences Ltd (2000c).

7.5. Repeat dose toxicity

TEST SUBSTANCE	TN-105
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Cr1:CD
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week;
Vehicle	Corn oil
Remarks - Method	GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	5/sex	15	0
III (mid dose)	5/sex	150	0
IV (high dose)	5/sex	400	0

Mortality and Time to Death

None.

Clinical Observations

Among high-dose animals, abnormal gait, loss of body tone and piloerection were observed during week 1, and piloerection also noted during the final two weeks of treatment. In addition, hair loss was observed in high-dose animals and a single male and female animal in mid-dose group during the treatment period.

Food consumption and bodyweight gains were decreased in high-dose animals during the first week, also in mid and high-dose males during weeks 2-4.

The functional observational battery (FOB) data showed that no behavioural changes were observed in test animals to be indicative of neurotoxicity.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No haematological changes were determined to be treatment related.

Clinical chemistry investigation showed an increase of alanine amino-transferase levels (ALT) in males of mid-dose and in both sexes of high-dose, and an increase of aspartate amino-transferase levels (AST) in both sexes of high-dose. Marginally higher total cholesterol levels followed a dosage related trend were noted in all treated female groups. In the high-dose group, increased potassium values in both sexes, increased urea levels in males and increased creatine levels in females were observed.

Pathology

The high-dose females had higher liver weights when compared with the controls.

Macroscopic examination revealed that an increased incidence of hair loss in both sexes and gaseous distension of the caecum in high-dose females.

Histopathology
No treatment-related changes were observed in microscopic examinations.

Remarks – Results
The changes of food consumption, bodyweight gain, and blood chemistry parameters in high-dose animals, and, to a lesser extent, in mid-dose males were considered to be treatment-related in this study

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 15 mg/kg bw/day in this study, based on the changes of food consumption, bodyweight gain, and blood chemistry parameters.

TEST FACILITY Huntingdon Life Sciences Ltd (2001b).

7.6. Genotoxicity - bacteria

TEST SUBSTANCE TN-105

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Test 1: Plate incorporation procedure
Test 2: Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0-5 000 µg/plate. b) Without metabolic activation: 0-5 000 µg/plate.
Vehicle	DMSO
Remarks - Method	GLP & QA.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>5 000		>5 000	
Test 1		>5 000		Not observed.
Test 2		>5 000		Not observed.
Present	>5 000		>5 000	
Test 1		>5 000	>5 000	Not observed.
Test 2		>5 000	>5 000	Not observed.

Remarks - Results
No substantial increases in revertant colony numbers over control counts were obtained with any of the tester strains following exposure to TN-105 at any concentration in either the presence or absence of S9 mix.

No visible thinning of the background lawn of non-revertant cells was obtained following exposure to TN-105.

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

TEST FACILITY Huntingdon Life Sciences Ltd (1999e).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	TN-105
METHOD	Ready Biodegradability: CO_2 Evolution Test. Modified Sturm Test (Procedure C.4-C of the Annex to Directive 92/69/EEC; OECD TG 301 B)
Inoculum	Activated sludge from sewage treatment works, which treats predominantly domestic waste.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC, DOC
Remarks - Method	In addition to the test substance, blank samples and samples containing a reference substance were measured.

RESULTS

Test substance			*Sodium Benzoate*	
Day	*% degradation Culture 1*	*% degradation Culture 2*	*Day*	*% degradation*
6	1	0	6	64
10	1	1	10	74
28	2	2	28	82

Remarks - Results	Degradation of the reference substance indicates that the test system was valid. It also degraded in the presence of the test substance indicating that the test substance is not inhibitory to micro-organisms. Mean cumulative CO_2 production by mixtures containing the test substance was negligible (equivalent to 2% of the theoretical CO_2 value by the end of the test.
CONCLUSION	The test substance is not readily biodegradable according to the OECD criteria requiring > 60% within 10 days of commencement.
TEST FACILITY	Huntingdon Life Sciences Ltd (2000d)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. The low water solubility and the high estimated adsorption coefficient may indicate a potential for bioaccumulation, however, there will be very little, if any release to the aquatic compartment.

8.2. Ecotoxicological investigations

The notifier has provided the following three studies. In all three studies a reliable method of analysis to distinguish between the test substance and the breakdown product di-tert-butylsalicylic acid (DTBS) could not be produced. Therefore, the aqueous test solutions have not been analysed. Based on the spectrophotometric analysis of the stock solutions, the aqueous test concentrations were assumed to be nominal.

Nominal exposure concentrations quoted in the three reports are stated to refer to the test substance as received with no allowance made for a purity of less than 100%.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	TN-105
METHOD	OECD TG 203 Fish, Acute Toxicity Test - 96 hour Semi-static conditions
Species	Rainbow trout (*Oncorhynchus mykiss*)

Exposure Period	96 hours
Auxiliary Solvent	Tetrahydrofuran (THF)
Water Hardness	Between 144 and 174 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometric analysis of stock solutions, which allowed distinguish between TN-105 and a breakdown product di-tert-butylsalicylic acid (DTBS) in aqueous solution. The use of an auxiliary solvent (THF) was found to be necessary to aid dispersal of the test substance in aqueous medium in all test concentrations.

RESULTS

Concentration mg/L Nominall	*Replicate*	*Number of Fish*	*Mortality*					
			0.25 h	*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
0.33	1	10	0	0	0	0	0	0
	2	10	0	0	0	0	0	0
0.65	1	10	0	0	0	0	0	0
	2	10	0	0	0	0	0	0
1.3	1	10	0	0	0	0	0	0
	2	10	0	0	0	0	0	0
2.5	1	10	0	0	0	0	0	2
	2	10	0	0	0	0	2	2
5.0	1	10	0	0	0	9	10	10
	2	10	0	0	1	9	10	10

LC50	> 5 mg/L between 0.25-24 hours. 4.1 mg/L at 48 hours. 3.0 mg/L at 72 hours. 2.8 mg/L at 96 hours.
NOEC	1.3 mg/L at 96 hours.
Remarks – Results	The highest test concentration resulting in 0% mortality and lowest test concentration resulting in 100% mortality were 1.3 and 5.0 mg/L, respectively. Marked reactions to exposure (other than death) were increased pigmentation, loss of equilibrium, hyperventilating, severe loss of equilibrium, swimming at the surface, slight loss of equilibrium, erratic swimming and resting at the bottom of the tank.

CONCLUSION — According to the criteria of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), the test substance is toxic to rainbow trout (OECD 2001).

TEST FACILITY — Huntingdon Life Sciences Ltd (2001c)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE — TN-105

METHOD — OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static conditions

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Tetrahydrofuran (THF)
Water Hardness	< 180 mg $CaCO_3$/L
Remarks - Method	The test organisms were maintained and the tests conducted in a reconstituted medium softened Elendt M4. The concentrations of $MgSO_4.7H_2O$, KCl and $NaHCO_3$ given in the protocol for Softened Elendt M4 medium as 61.5 mg/L, 5.8 mg/L and 64.8 mg/L were incorrect. The actual amounts used in the study to provide a medium with the required softness were 61.7 mg/L, 2.9 mg/L and 32.4 mg/L of

$MgSO_4.7H_2O$, KCl and $NaHCO_3$, respectively. This deviation from protocol is not considered to have affected the outcome or validity of the study.

The test substance was initially dissolved in THF to give a main solvent stock solution and serial dilutions of this main solution were performed to give the remaining solvent stock solutions. Aliquots of 50 µL of each solvent stock solution were added to 500 mL of softened Elendt M4 to give the final test series with the nominal concentrations given below. The concentrations of the solvent stock solutions were analysed at 0 and 24 hours that indicated the concentrations were between 97% and 100% of the nominal. The report however, does not include any comment on the presence of any precipitates of test substance.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal	*(10 per replicate)*	*24 h [acute]*	*48 h [acute]*
0.10	20	0	0
0.17	20	1	1
0.33	20	0	14
0.65	20	6	20
1.3	20	17	20
2.5	20	20	20
5.0	20	20	20

LC50	0.80 mg/L at 24 hours 0.28 mg/L at 48 hours
NOEC	0.17 mg/L at 48 hours
Remarks - Results	A single daphnia was immobilised at 0.17 mg/L after 24 hours, however, this was not considered to be biologically significant. The highest test concentration resulting in 0% mortality and lowest test concentration resulting in 100% mortality were 0.10 and 0.65 mg/L, respectively.

CONCLUSION According to GHS criteria the test substance is very toxic to daphnia (OECD 2001).

TEST FACILITY Huntingdon Life Sciences Ltd (2001d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE TN-105

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	Unicellular green alga (*Selenastrum capricornutum*)
Exposure Period	96 hours
Concentration Range Nominal	Five test concentrations between 0.33 to 5.0 mg/L
Auxiliary Solvent	Tetrahydrofuran (THF)
Water Hardness	Not reported.
Remarks - Method	The following deviations from protocol occurred, however, were not considered to have affected the integrity of the study: Cell counts were not conducted at 0 hours as the cell density was too low to be accurately counted. Therefore, based on the cell counts of the algal pre-culture, it was estimated to be approximately 1 x 10^4 cells/ml. An additional measurement was made at 72 hours to assess the progress of the study and to justify its continuation up to 96 hours.

Growth was substantially inhibited in replicate 3 at 0.33 mg/L test concentration after 48 hours, in comparison with the other two replicates. This observation could not be explained therefore, the replicated was excluded from statistical analysis of the results.

RESULTS

Effect *mg/L*	*Biomass* *mg/L*	*Growth* *mg/L*
EC50 at 72 hours	2.3	> 5.0
EC50 at 96 hours	1.8	> 5.0

NOEC 0.65 mg/L

CONCLUSION The test substance inhibited the growth of *Selenastrum capricornutum* at concentrations tested in excess of 0.65 mg/L. In accordance with the GHS criteria, it is toxic to algae (OECD 2001).

TEST FACILITY Huntingdon Life Sciences Ltd (2001e)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure of the toner containing the notified chemical will result from the disposal of printed paper and discarded cartridges and from any accidental leakage of the cartridges during use. Release due to leakage is not expected under normal use as the cartridge is designed to prevent leakage. However, if leakage does occur, the toner will be contained and presumably disposed of to landfill. Toner residues contained in the empty cartridges are expected to be about 10% of the import volume and to remain within these containers, although release could occur from deterioration of the cartridge.

Some waste paper will be disposed of directly to landfill with the notified chemical strongly bound to the paper. The total import volume of the notified chemical will ultimately be either disposed of to landfill or incinerated or recycled with paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance. Incineration of waste paper and sludge will destroy the compound with the generation of water vapour, oxides of carbon and zirconium salts.

During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30-60% of the total amount of toner and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill.

The low water solubility and the high estimated adsorption coefficient of the notified chemical may indicate a potential for bioaccumulation, which is offset by the low aquatic exposure.

The very limited exposure to the aquatic compartment makes it very difficult to calculate a meaningful predicted environmental concentration (PEC).

9.1.2. Environment – effects assessment

The results of the ecotoxicological studies indicate the notified chemical is toxic to rainbow trout and algae and very toxic to daphnia. A predicted no effect concentration (PNEC) calculated using the LC50 of the most sensitive species and a safety factor of 100 (OECD) would be 2.8 µg/L.

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. 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.

It is not possible to determine a realistic PEC value in order to assess the risk to aquatic organisms, as the use pattern of the notified chemical will result in negligible exposure to the aquatic environment. The estimated PNEC of 2.8 µg/L is very low. However, due to the diffuse nature of use and limited release to water, it is unlikely that the chemical would exist at levels which could accumulate and pose a threat to aquatic organisms or bioaccumulate. The resulting PEC/PNEC can be expected to be much lower than one.

Any small amount that enters aquatic environment is likely to be immobilised through adsorption onto soil particles and sediments. Based on the import volume, method of packaging and low concentration of the notified chemical in the toner product, release of the notified chemical to the environment is expected to be low and widespread. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified chemical as it is not readily biodegradable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

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

Dermal and inhalation exposure of maintenance workers to the notified chemical is possible during routine maintenance but is expected to be low due to the low concentration of the notified chemical in the toner. Nevertheless, due to the probable fine nature of the toner, skin, eye and respiratory exposure should be avoided. The national exposure standard for nuisance dusts is 10 mg/m3 TWA (NOHSC, 1995). Australia has no exposure standard for respirable dust, however, the ACGIH TLV of 3 mg/m^3 TWA is recommended (ACGIH, 2001). Due to their frequent exposure to toners, maintenance personnel should wear cotton or disposable gloves. However, the design of the cartridges is such that exposure to the notified chemical should be low. The predicted airborne concentration of toner dust in the vicinity of a photocopier is <0.1 mg/m^3 (EASE).

9.2.2. Public health – exposure assessment

The notified chemical will not be available to the public. Members of the public may come into contact with printed paper containing the notified chemical.

9.2.3. Human health - effects assessment

TN-105 was of low acute oral toxicity (LD50>2 000 mg/kg) in rats. It was non-irritating to rabbit skin but slightly irritating to rabbit eyes.

In the skin sensitisation study, positive responses were observed in both test and control animals when challenged with 60% TN-105 but not with 30% TN-105. The study report stated that these positive responses were caused by mechanical damage at bandage removal when the challenge concentration was high. The same test animals were used for the second challenge and negative responses were observed after the second challenge with slightly lower concentrations (40 and 20%). Combined all results from this study, TN-105 is not considered to be a skin sensitiser.

A 28-day oral toxicity study in rats was provided. The NOAEL was established as 15 mg/kg/day in this study based on the changes of food consumption, bodyweight gain and blood chemistry parameters.

In the Ames test, TN-105 was not mutagenic to bacteria under the conditions of the test.

Based on the available information, TN-105 is not 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 OHS risk presented by the notified chemical is expected to be low due to the low potential for worker exposure and the low concentration of the notified chemical in the imported product. However, due to the fine nature of the toner, there is risk of mechanical irritation if the toner is inhaled.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

The notified chemical will not be available to the public. Members of the public may make dermal contact with printed paper containing the notified chemical. However, the risk to public health will be negligible because the notified chemical is present at low concentrations and unlikely to be bioavailable.

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.*

10.2. Environmental risk assessment

On the basis of the information provided on its proposed use pattern, the overall environmental hazard from the notified chemical is considered to be low.

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 under the conditions described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the products containing the chemical provided by the notifier were 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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in the toners:
  - Toners should be changed in a well-ventilated area.
  - Avoid dust clouds.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the toners:
  - Gloves.

  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 MSDS recommends that the notified chemical should not be disposed of to drains and not allowed to enter waterways and sewage systems. Disposal should be either by incinerating waste or to an authorised waste collection point in accordance with local, state or national legislation.

Emergency procedures

- Any accidental spills should be contained and removed using water and placed in sealable containers and disposed of as described in the MSDS.

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 subsection 64(1) of the Act; if
  - the notified chemical itself is imported or manufactured in Australia;
  - the import volume exceeds one tonne;
  - new uses with higher aquatic exposure are proposed, where a separate notification with a full suite of ecotoxicity studies should be supplied due to the high aquatic toxicity, persistence and potential to bioaccumulate. This notification should also address bioaccumulation and provide a comprehensive exposure analysis.

or

(2) Under subsection 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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