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September 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

W-663

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Brother International (Aust.) Pty Ltd (ACN 17 001 393 835) of 7 Khartoum Road NORTH RYDE NSW 2113.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, flammability, acute inhalation toxicity, Daphnia reproduction study.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Europe (Nos. 02-00-0808-00 and 02-00-0818-00).

2. IDENTITY OF CHEMICAL

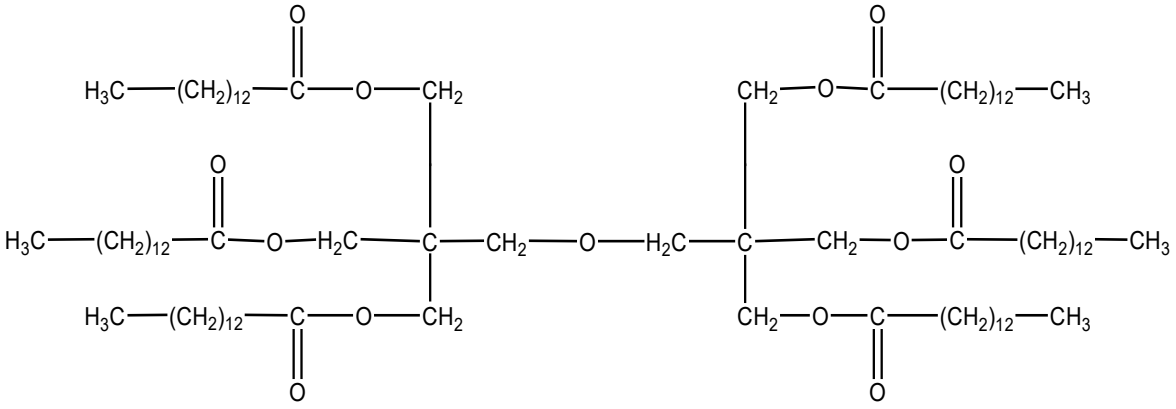
CHEMICAL NAME
Tetradecanoic acid, 2-[[3-[(1-oxotetradecyl)oxy]-2,2-bis[[(1-oxotetradecyl)oxy]methyl]propoxy] methyl]-2-[[(1-oxotetradecyl)oxy]methyl]-1,3-propanediyl ester

OTHER NAME(S)
Dipentaerythritol hexamyristate
2,2,6,6-tetrakis(tetradecanoyloxymethyl)-4-oxa-heptene-1,7-diyl ditetradecanoate

CAS NUMBER
75587-84-7

MOLECULAR FORMULA
$C_{94}H_{178}O_{13}$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
1516.44

SPECTRAL DATA

METHOD Ultraviolet/visible spectroscopy.
Remarks Peak at 238 nm with a molar extinction coefficient of 39.63.

METHOD Infrared spectroscopy.
Remarks Peak assignments (cm^{-1})
C-H: 2960.7, 2852.4, 1469.6, 717.6.
C=O: 1741.0
C(=O)-O-C: 1177.1
C-O-C: 1101.1

METHOD Nuclear magnetic resonance spectroscopy.
Remarks ^{1}H (ppm): 0.88 (methyl), 1.26, 2.29, 3.39, 4.07 (methylene)
^{13}C (ppm): 14.10 (methyl), 22.68 – 34.10 (methylene), 42.68 (>C<), 62.34 (-COO$\underline{C}H_2$-), 69.98 (-$\underline{C}H_2O\underline{C}H_2$-), 173.18 (carbonyl).

3. COMPOSITION

DEGREE OF PURITY
95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name Myristic acid
CAS No. *Weight %* 0.5%
Hazardous Properties Moderate skin irritant, mild eye irritant (TomesPlus, 2004).

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name Dipentaerythritol pentamyristate
CAS No. *Weight %* 4.5%

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported as a component of toner in cartridges at ≤ 6%.

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

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

USE
Additive in toner used for printing.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
Standard toner cartridges wrapped in enclosed black plastic bags in cardboard cartons transported by road to distributors.

5.2. Operation description

To change the cartridge in a photocopier or printer, the seal tape is removed and the cartridge is placed into the copying machine or printer. The cartridge is designed not to release the toner until the seal tape is removed.

During the copying or printing operation, the toner will be transferred on to the paper and fixed by heat.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	< 10	< 8 hours per day	< 230 days per year
Office workers	10 - 100	10' per day	< 10 days per year
Maintenance workers	< 10	< 8 hours per day	< 230 days per year

Exposure Details
Office workers and printer/photocopier maintenance workers may be intermittently exposed to the notified chemical when replacing the spent cartridge, and during maintenance and cleaning of printers or photocopiers. Maintenance workers may potentially come in contact with the notified chemical more often than office workers. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if there is spillage. However, exposure is expected to be controlled through the design of the toner cartridge and the printing and photocopier machines. Printer and photocopier maintenance personnel often wear cotton disposable gloves. Toner cartridges are sealed and worker exposure to the toner should be minimised by the use of the replacement procedures recommended by the manufacturer.

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

Contact with paper printed with toners containing the notified chemical is unlikely to result in dermal exposure, as it will be heat fixed in the structure of the paper.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The toner containing up to 6% of the notified chemical will be imported in sealed cartridges. Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. Environmental release of the notified chemical from cartridges during importation, transportation and storage is unlikely.

RELEASE OF CHEMICAL FROM USE

The toner cartridges will not be opened during installation, replacement or use. Therefore, release of toner containing the notified chemical to the environment is not expected under conditions of normal use. In the event of an accidental leakage individual container capacity, and container and packaging specifications would limit the extent of release and the majority of the spill will be collected and placed in a suitable container to be disposed of to landfill. No direct release to water occurs during normal use but a small amount of the chemical is expected to be lost to air during the printing process.

The empty toner cartridges (each containing 4 to 7 g of the notified chemical) will be either collected for recycling by a recycling company or disposed of to landfill in the normal office garbage. It is expected that approximately 49.5% of the imported notified chemical will be disposed of to landfill and approximately 0.5% or greater amount will be recovered by recycling programs. Therefore, based on a maximum import volume of 3 tonnes, up to 1500 kg (50%) of the notified chemical will be strongly bound to printed paper, which will be disposed of to landfill, recycled or incinerated.

During the paper recycling process, the paper will be repulped in water, cleansed of contaminants, deinked with alkali, washed, cooked, bleached, screened and then used in the normal paper production process. The alkali mixture resulting from the deinking stage is most likely recycled or neutralised and disposed of to a wastewater treatment plants (WWTP) by a licensed waste contractor. It is expected that the notified chemical contained in the toner removed from the paper/pulp during deinking will mostly move to sludge due to its low water solubility.

5.5. Disposal

The total import volume of the notified chemical will ultimately be disposed of either to landfill or by incineration or recycling with paper except for approximately 15 kg of the chemical that is expected to be recovered annually via a cartridge recycling program.

5.6. Public exposure

The public may be intermittently exposed to the notified chemical when replacing the spent cartridges, and during maintenance and cleaning of home printers or photocopiers. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if spillage occurs. Exposure is expected to be controlled through the design of the toner cartridge and the printing and photocopier machines. Toner cartridges are sealed and public exposure to the toner should be minimised by the use of the replacement procedures recommended by the manufacturer.

Contact with paper printed with toners containing the notified chemical is unlikely to result in dermal exposure, as it will be heat fixed in the structure of the paper.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White powder.

Melting Point/Freezing Point 62.4°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks	Method: differential scanning calorimetry.
TEST FACILITY	Huntingdon Life Sciences (2002a).

Boiling Point > 164.8°C at 101.3 kPa

METHOD	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Method: differential scanning calorimetry.
TEST FACILITY	Huntingdon Life Sciences (2002a).

Density 1010 kg/m^3 at 20°C

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method.
TEST FACILITY	Huntingdon Life Sciences (2002a).

Vapour Pressure 1.21 X 10^{-7} kPa at 25°C

METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure (Vapour Pressure Balance)
TEST FACILITY	Huntingdon Life Sciences (2002a).

Water Solubility < 1.02 x 10^{-3} g/L at 20°C

METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility (Flask Method).
Remarks	Preliminary test results showed that the water solubility of the test substance was less than 10 mg/L. As the solubility was below the limit of detection of the column elution method, the flask method with HPLC detection was used. No peaks were observed for the test solutions therefore the water solubility was estimated to be less than the limit of detection estimated from use of standard solutions.
TEST FACILITY	Huntingdon Life Sciences (2002a).

Fat (or n-octanol) Solubility > 1016.9 mg/L Standard fat at 37°C

METHOD	OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks	Liquefied and mixed standard fat (100 mL) was stirred in a water bath at 37°C while adding small quantities of the test substance sequentially and dissolving over time. The test was terminated after an extended period of stirring (> 3 months) as there was no sign of reaching a saturated solution. The report noted that transesterification might have occurred during the test modifying the structure and molecular weight of the test substance allowing it to dissolve more readily.
TEST FACILITY	Huntingdon Life Sciences (2002a).

Hydrolysis as a Function of pH Not determined.

Remarks	The test was not conducted due to the low water solubility of the notified chemical. The notified chemical contains ester linkages that could undergo hydrolysis under extreme pH conditions. However, significant hydrolysis is unlikely to occur in the environmental pH range of 4 to 9.

Partition Coefficient (n-octanol/water) log P_{ow} > 6

Remarks	Due to the low water solubility and poor sensitivity of the test substance to ultraviolet and refractive index detection, the partition coefficient could not be

determined using either the HPLC Method or the Shake Flask Method. An attempt was made to calculate the partition coefficient using the ratio of solubilities of the test substance in octanol and water (using a combination of the Shake Flask Method and visual inspection to determine the octanol solubility of the test substance). This was not successful as both water and octanol solubilities were below the limit of detection.

An estimate of log P_{ow} was derived using the SRC LOGKOW v1.63 software. This result should be interpreted with caution, as the particular QSAR method is known to overestimate the log P_{ow} for long chain aliphatic compounds with repetitive structures. However the log P_{ow} can be predicted to be high.

The high log P_{ow} is consistent with the low water solubility indicating high affinity for the organic phase and component of soils and sediments.

TEST FACILITY Huntingdon Life Sciences (2002a).

Adsorption/Desorption log $K_{oc} > 6$

Remarks It was not possible to determine the soil adsorption coefficient using the HPLC method due to the poor water solubility of the test substance and its poor sensitivity to ultra violet and refractive index detection. A log K_{oc} value was estimated using the SRC PCKOCWIN v.1.65 software. It is noted in the report that the method is based upon fragment contributions, which could overestimate the K_{oc} value of long chain aliphatic compounds such as the test substance. However, the log K_{oc} can be predicted to be high.

The high K_{oc} value is consistent with the low water solubility and high log P_{ow} and indicates strong adsorption to and low mobility in soils.

TEST FACILITY Huntingdon Life Sciences (2002a).

Dissociation Constant Not determined.

Remarks Due to the low water solubility of the notified chemical, determination of its dissociation constant was not technically feasible. There are no groups likely to dissociate.

TEST FACILITY Huntingdon Life Sciences (2002a).

Particle Size

METHOD Sieve analysis.

Range (μm)	*Mass (%)*
> 400	64.1
400 – 125	27
125 – 75	4.5
75 – 30	4.1
30 – 10	0.6
< 10	0

TEST FACILITY Huntingdon Life Sciences.

Flash Point Not determined.

Remarks Not determined as substance is a solid.

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
TEST FACILITY Huntingdon Life Sciences (2002a).

Autoignition Temperature > 400ºC

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Huntingdon Life Sciences (2002a, 2003a).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Huntingdon Life Sciences (2002a).

Oxidising Properties Non-oxidising.

METHOD 92/69/EEC A.17 Oxidising Properties.
TEST FACILITY Huntingdon Life Sciences (2002a).

Reactivity

Remarks Stable under normal environmental conditions.

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.
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	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/Hsd Sprague-Dawley.
Vehicle	Corn oil.
Remarks - Method	No deviations from protocol.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	None.
Effects in Organs	None.

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

TEST FACILITY — Huntingdon Life Sciences (2002b).

7.2. Acute toxicity - dermal

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Hsd Sprague-Dawley.
Vehicle	None.
Type of dressing	Occlusive.
Remarks - Method	No deviations from protocol.

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	None.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.

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

TEST FACILITY Huntingdon Life Sciences (2002c).

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
Vehicle	None.
Observation Period	4 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	No deviations from protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0		0
Oedema	0	0	0	0		0

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

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Huntingdon Life Sciences (2002d).

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	3 days.
Remarks - Method	No deviations from protocol.

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	1.33	0.67	0	2	3 days	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge						
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY	Huntingdon Life Sciences (2002e).

7.5. Skin sensitisation

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 406 Skin Sensitisation – maximisation test. EC Directive 96/54/EC B.6 Skin Sensitisation - maximisation.
Species/Strain	Guinea pig/Dunkin-Hartley.
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% (w/v) topical: 65% (w/v)
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal: 5% (w/v) topical: 65% (w/v)
Signs of Irritation	None due to notified chemical.
CHALLENGE PHASE	
1st challenge	topical: 32.5% (w/v), 65% (w/v)
Remarks - Method	No significant deviations from protocol.

RESULTS

Remarks - Results	No sensitisation reactions were observed in any animal at either challenge concentration at either 24 or 48 hours after patch removal.
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 (2002f).

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. OPPTS 870.3050, July 2000.
Species/Strain	Rat/Crl: CD SD IGS BR.
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week.
Vehicle	Corn oil.
Remarks - Method	The actual concentration of the low dose could not be quantitated. The concentration is therefore the nominal value.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0
II (low dose)	"	15	0
III (mid dose)	"	150	0
IV (high dose)	"	1000	0

Clinical Observations

Lack of auditory startle reflex in 2/5 high dose females. No effect on food consumption or bodyweight gain.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No treatment related effects.

Effects in Organs
No treatment related effects.

Remarks – Results	A lack of auditory startle reflex in high dose females was associated with treatment but was not considered to be of neurotoxicological importance due to a lack of treatment related response in other clinical findings or neurobehavioural screening parameters. Low neutrophils in mid and high dose females were not dosage related and were within the concurrent control range so were not considered to be treatment related.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the lack of significant findings at the high dose.

TEST FACILITY	Huntingdon Life Sciences (2002g).

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. US OPPTS 870.5100. Japanese Ministry of Agriculture, Forestry and Fisheries (1985). Notification of the Director General, Agricultural Production Bureau. Nohsan No. 4200. Joint Directives of J EPA, J MHW and J MITI (31 October 1997) Kanpoan No. 287, Eisei No. 127 and Kikyoku No. 2 (31 October 1997). JMHW Genotoxicity Testing Guideline, PAB Notification No. 1604 (1 November 1999). Plate incorporation procedure and repeat with Pre incubation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102. *E. coli*: WP2uvrA (pKM101).
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 5 - 5000 µg/plate. b) Without metabolic activation: 5 - 5000 µg/plate.
Vehicle	DMSO.
Remarks - Method	The first experiment was by plate incorporation, the repeat experiment by preincubation.

RESULTS

Remarks - Results	No signs of toxicity were observed in either replicate test. No increase in revertant number was seen in any strain at any dose. Positive control substances gave the expected mutagenic activity.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (2002h).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
EC Directive 2000/32/EEC B.10. In vitro Mammalian Chromosome Aberration Test.
US EPA Health Effects Test Guidelines. OPPTS 870.5375. EPA 712-C-98-223.

Cell Type/Cell Line Human lymphocytes.
Metabolic Activation System Aroclor induced rat liver S9 fraction.
Vehicle DMSO.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 39.06, 78.13, 156.25, 312.5, 625, 1250*, 2500*, 5000*	3 hours	20 hours
Test 2	0, 156.25, 312.5, 625, 1250*, 2500*, 5000*	20 hours	"
Present			
Test 1	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*, 2500, 5000	3 hours	"
Test 2	0, 625, 1250*, 2500*, 5000*	3 hours	"

Remarks - Method No significant deviations from protocol.

RESULTS

Remarks - Results Mitotic index was reduced to a maximum of approximately 90% of control at the top dose. Positive controls gave the expected responses and negative controls were as expected.

No cytotoxicity or precipitation of the test substance was observed and there was no increase in the frequency of chromosomal aberrations in the treated cultures over the control values.

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

TEST FACILITY Huntingdon Life Sciences (2002i).

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 (Modified Sturm Test).
Inoculum	Activated sludge collected from sewage treatment works that treats predominantly domestic waste.
Exposure Period	29 days.
Auxiliary Solvent	None.
Analytical Monitoring	CO_2 Evolved.
Remarks - Method	In addition to the test substance (10 mgC/L), blank samples and samples containing a reference substance (sodium benzoate at 10 mg/L)) were measured.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% degradation*	*Day*	*% degradation*
2	0	2	21
6	1	6	60
10	1	10	72
21	1	21	79
29	1	29	84

Remarks - Results	Degradation of the reference substance (60% after 6 days and 84% after 29 days) indicates that the test system was valid.
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 (2002j).

8.1.2. Bioaccumulation

No bioaccumulation data were provided. The low water solubility, high fat solubility and the high estimated partition coefficient may indicate a potential for bioaccumulation (Connell, 1989). The fat solubility test report (summarised in Section 6) notes that the high fat solubility observed could have been due to transesterification, which may have modified the structure and the molecular weight of the notified chemical during the test and allowed it to dissolve more readily.

Due to the high molecular weight of the notified chemical it is not expected to cross biological membranes. Further, the limited release to the aquatic environment, if any, should reduce the availability of the notified chemical 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 and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Semi-static.
Species	Rainbow trout (*Oncorhynchus mykiss*).

Exposure Period	96 hours.
Auxiliary Solvent	None.
Water Hardness	141 to 161 mg $CaCO_3$/L.
Analytical Monitoring	Test concentrations were not analytically monitored as a sufficiently sensitive method with a limit of detection below the limit of aqueous solubility of the notified chemical (determined to be < 1 mg/L as summarised in Section 6) was not available.
Remarks – Method	A 100% saturated aqueous solution was prepared by stirring the notified chemical with water for 72 hours and filtered (0.45 μm cellulose nitrate membrane filters). Based on a preliminary range finding study with concentrations up to the saturation level, the definitive study was conducted at the saturation level only. The control and test media were renewed daily. The report does not comment on the clarity of the test substance solution during the test.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*						
		0.25 h	*2 h*	*4 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0	0	0	0
100*	10	0	0	0	0	0	0	0

* Assumed to be the limit of water solubility under test conditions.

LC50	>100% saturation at 96 hours.
NOEC (or LOEC)	>100% saturation at 96 hours.
Remarks – Results	Oxygen content (9.1 to 9.2 mgO_2/L in control and 9.2 to 9.3 mgO_2/L in the test substance solution), pH (7.1 to 7.6 in control and 7.3 to 7.6 in test substance solution) and temperature (14°C in control and 13 to 14°C in test substance solution) were all satisfactorily maintained. No abnormalities or sub-lethal effects were observed in the control or test media.

CONCLUSION The test substance is not toxic to fish up to the limit of its aqueous solubility under the test conditions.

TEST FACILITY Huntingdon Life Sciences (2003b).

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test and EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static.

Species	*Daphnia magna*
Exposure Period	48 hours.
Auxiliary Solvent	None.
Water Hardness	Standard medium (Elendt M4) was used.
Analytical Monitoring	Test concentrations were not analytically monitored for the same reasons mentioned in section 8.2.1.
Remarks - Method	The test substance was stirred with the test medium to prepare a 100% saturated aqueous solution using the same method described in section 8.2.1. Based on a preliminary range finding study (using nominal concentrations of 1, 10 and 100% of saturation) the definitive study was conducted at the 100% saturation level. No allowance was made for a purity of less than 100%.

The exposure concentrations were not verified. The report does not comment on the clarity of the test substance solution during the test.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*% Immobilised*	
		24 h	*48 h*
Control	20	0	0
100*	20	0	0

* Assumed to be the limit of water solubility under test conditions.

LC50	>100% saturation at 48 hours.
NOEC (or LOEC)	>100% saturation at 48 hours.
Remarks - Results	Oxygen content (8.4 to 8.7 mgO_2/L in controls and 7.9 to 8.6 mgO_2/L in the test substance solutions), pH (7.2 to 7.5 in controls and 7.3 to 7.7 in test substance solutions) and temperature (20°C in controls and 20 to 21°C in test substance solutions) were all satisfactorily maintained.
CONCLUSION	The test substance is not toxic to Daphnia up to the limit of its aqueous solubility under the test conditions.
TEST FACILITY	Huntingdon Life Sciences (2003c).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test and EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Selenastrum capricornutum* (Strain No. CCAP 278/4)
Exposure Period	72 hours.
Concentration Range	
Nominal	100% saturation
Auxiliary Solvent	None.
Water Hardness	Standard sterile nutrient medium was used.
Analytical Monitoring	Test concentrations were not analytically monitored due to the same reasons mentioned in section 8.2.1.
Remarks - Method	The test substance was stirred with the nutrient medium to prepare a 100% saturated aqueous solution using the same method described in 8.2.1. Based on a preliminary range finding study (using nominal concentrations of 1, 10 and 100% of saturation) the definitive study was conducted at the 100% saturation level. No allowance was made for a purity of less than 100%. The test water temperature (23.4°C at 0 hours and 23.8°C at 72 hours) and pH (7.0 to 7.3 in the controls and 7.1 in the test substance solutions) were satisfactorily maintained. The temperature and light intensity were not recorded for 24 and 48 hours. This omission in recording is stated not to have affected the validity of the study as also shown by the increase in algal growth by 6 fold for each period from 0 to 24, 24 to 48 and 48 to 72 hours. The exposure concentrations were not verified. The report does not comment on the clarity of the test substance solution during the test.

RESULTS

Growth - E_rC50 (0-72 h)	*Biomass - E_bC50 (72 h)*	*NOEC at 72 h*
>100% saturation	>100% saturation	>100% saturation

Remarks - Results: No abnormalities were found in any algal cells when examined microscopically.

CONCLUSION: The test substance is not toxic to algae up to the limit of its aqueous solubility under the test conditions.

TEST FACILITY: Huntingdon Life Sciences (2003d).

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 and OPPTS Method 850.6800.

Inoculum: Activated sludge obtained from a sewage treatment plant that treats predominantly domestic sewage.

Exposure Period: 3 hours

Concentration Range

Nominal: 1, 10 and 100 mg/L

Remarks – Method: A preliminary solubility trial showed that a suitable aqueous stock solution could not be prepared due to the low solubility of test substance. Therefore, appropriate weights of the test substance were added to dechlorinated water and treated with ultrasound for 10 minutes to prepare the 1, 10 and 100 (in triplicate) mg/L test solutions.

Test concentrations of the reference substance (3,5-dichlorophenol) were 3, 10 and 32 mg/L.

RESULTS

IC50: >100 mg/L

NOEC: >100 mg/L (highest concentration tested)

Remarks – Results: No effect on sludge respiration was observed at any of the test concentrations. The IC50 of the reference substance calculated by the Moving Average method was 7.0 mg/L (95% confidence limits 5.5-8.7 mg/L), thus validating the test.

CONCLUSION: The test substance does not inhibit the respiration of activated sludge.

TEST FACILITY: Huntingdon Life Sciences (2002k).

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. The notifier expects that toner residues in cartridges containing approximately 49.5% of the notified chemical to be disposed of to landfill. In a landfill, the chemical will eventually be released due to deterioration of the cartridge but can be expected to be immobile due to its low water solubility and estimated high log K_{oc}.

Up to 50% (1500 kg) of the imported notified chemical strongly bound to printed paper will be disposed of to landfill (directly or bound to sludge resulting from paper recycling) or by incineration. During paper recycling, it is expected that the notified chemical contained in the toner removed from the paper/pulp during deinking will mostly move to sludge due to its low solubility. Therefore, most of the notified chemical in the recycled paper can be expected to be disposed of with sludge to landfill. Very little of the notified chemical is expected to partition to the supernatant water to be released to the sewer.

Due to its low water solubility the notified chemical entering soils via landfill (fixed to paper, adsorbed to sludge, or released from ruptured cartridges) is not expected to be mobile and enter the aquatic compartment. Although it is not readily biodegradable, the chemical is expected to eventually become associated with soil and sediment and undergo slow degradation by biotic and abiotic processes. Incineration of waste paper and sludges will destroy the compound with the generation of water vapour and oxides of carbon.

The low water solubility and the high estimated adsorption coefficient of the notified chemical may indicate a potential for bioaccumulation, which is expected to be offset by the high molecular weight and 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 not toxic to rainbow trout, Daphnia and algae up to the limit of its water solubility. Therefore, it was not possible to calculate a predicted no effect concentration (PNEC).

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. During paper recycling processes almost all of the notified chemical can be expected to adsorb to sludge, which is dried and disposed of to landfill or incinerated.

It is not possible to determine a realistic PEC value, as the use pattern of the notified chemical will result in limited exposure to the aquatic environment. The ecotoxicity text results show that the notified chemical is not toxic to aquatic organisms up to the limit of its water solubility. Therefore, a meaningful PNEC value cannot be derived in order to assess the risk to aquatic organisms. Although the chemical has the potential to bioaccumulate, due to the diffuse nature of use and limited release to water, it is unlikely that the chemical would exist at levels which could pose a threat of bioaccumulation. The high molecular weight will further reduce this potential.

Any small amount of the notified chemical that enters the 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

Office workers and printer maintenance workers may be intermittently exposed to the notified chemical when replacing the spent cartridge, and during maintenance and cleaning of printers or photocopiers. Service personnel are anticipated to have the greatest level of exposure. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if spillage occurs. Exposure to the notified chemical is expected to be low due to the design of the toner cartridges and the low concentration of the notified chemical. Exposure will be minimised by placing photocopiers and printers in areas of adequate ventilation and the use of disposable gloves by service personnel.

9.2.2. Public health – exposure assessment

The public may be intermittently exposed to the notified chemical when replacing the spent cartridge, and during maintenance and cleaning of home printers or photocopiers. Exposure would be principally by skin contamination, however, inhalation exposure could also occur, particularly if spillage occurs. Exposure to the notified chemical is expected to be low due to the design of the toner cartridges and the low concentration of the notified chemical. Exposure will be minimised by the use of the replacement procedures recommended by the manufacturer and placing photocopiers and printers in areas of adequate ventilation.

Exposure to the notified chemical in printed paper is expected to be negligible, as it will be bound in the structure of the paper.

9.2.3. Human health - effects assessment

The notified chemical was of low toxicity via the oral and dermal routes in rats (LD_{50} > 2000 mg/kg bw), was a not a skin irritant in rabbits and was a slight eye irritant in rabbits, was not a skin sensitiser in guinea pigs, did not exhibit any systemic toxicity in a 28-day repeat dose oral toxicity study in rats and was neither mutagenic in bacteria nor clastogenic in human lymphocytes 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, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is unlikely to be harmful via the oral, dermal or inhalation routes, is not likely to be irritating or sensitising in use and is not likely to be genotoxic. In addition it is present at 6% in the imported toner and the toner is packed sturdy cartridges packed in cardboard boxes typically plastic wrapped onto pallets. Exposure of transport or storage workers due to accidental rupture of cartridges should be rare.

During used office workers and maintenance workers should only be exposed to low levels of toner either by inhalation or dermal contact.

Overall, there is a low risk of adverse health effects to any workers coming in contact with the imported toner at any stage of importation, use or final disposal.

9.2.5. Public health – risk characterisation

Similar to office workers members of the public should only be exposed to low levels of imported toner at any stage of importation, use or disposal. Also given the low hazard of the notified chemical at a low concentration in the imported toner, there is a low health risk to the public.

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* (NOHSC, 2002).

As a comparison only, the classification of notified chemical/polymer 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.

It was not possible to classify the notified chemical for the environment according to the GHS criteria (United Nations, 2003).

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS 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

No special precautions are required for the notified chemical when used at low quantities in a toner in cartridges in electrophotocopying machines or electrophotographic printers. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed for use of toners containing the notified chemical:

- Avoid contact with skin and eyes.
- Avoid breathing dust
- Avoid generation of dust. Photocopiers and printers should be located in well ventilated areas. The NOHSC Exposure Standard of 10 mg/m^3 TWA for nuisance dust should be maintained in the workplace.

- Service personnel should wear cotton or disposable gloves when replenishing toner and servicing copying machines and 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.

Environment

Disposal

- Empty toner cartridges containing the notified chemical should be disposed of to landfill.

- Do not dispose the notified chemical into sewers or water bodies.

Emergency procedures

- Spills/release of the notified chemical should be handled by sweeping up and discarding in to a waste container.

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.

13. BIBLIOGRAPHY

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

Huntingdon Life Sciences (2002a) W-663 Physicochemical Properties. Project No. NPO 094/024322. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002b) W-663 Acute Oral Toxicity to the Rat (Acute Toxic Class Method). Project No. NPO 080/022255/AC. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002c) W-663 Acute Dermal Toxicity to the Rat. Project No. NPO 081/022256/AC. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002d) W-663 Skin Irritation to the Rabbit. Project No. NPO 082/022226/SE. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002e) W-663 Eye Irritation to the Rabbit. Project No. NPO 083/022352/SE. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002f) W-663 Skin Sensitisation to the Guinea Pig (Magnusson and Kligman Method). Project No. NPO 084/022424/SS. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002g) W-663 Toxicity Study by Oral Administration to CD Rats for 4 Weeks. Project No. NPO 086/024481. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002h) W-663 Bacterial Reverse Mutation Test. Project No. NPO 087/022206. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002i) W-663 In vitro Mammalian Chromosome Aberration Test in Human Lymphocytes. Project No. NPO 088/022348. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002j) W-663 Assessment of Ready Biodegradability – Modified Sturm Test. Project No. NPO 093/022447. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2002k) W-663 Activated Sludge – Respiration Inhibition Test. Project No. NPO 092/022270. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2003a) W-663 Autoignition Temperature (Liquids and Gases). Project No. NPO 102/032698. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2003b) W-663 Acute Toxicity to Fish. Project No. NPO 089/032490. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2003c) W-663 Acute Toxicity to *Daphnia magna*. Project No. NPO 090/032491. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

Huntingdon Life Sciences (2003d) W-663 Algal Growth Inhibition Assay. Project No. NPO 091/032492. Huntingdon Life Sciences, Cambridgeshire, England (unpublished report submitted by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

TomesPlus (2004) http://csi.micromedex.com.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.