File No: STD/1178

December 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NT-24

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Director
NICNAS

FULL PUBLIC REPORT

NT-24

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd (ABN 66 005 002 951)
1 Thomas Holt Drive
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:
Chemical identity
Purity and nature of impurities
Import volume
Identity of sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Flashpoint
Acute inhalation toxicity
Germ cell toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NT-24

METHODS OF DETECTION AND DETERMINATION

METHOD	UV/visible, IR, MS, HPLC
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99.6%

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as an ingredient at < 2% of toner bottles or cartridges, to be used in copiers and printers

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

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

USE
Ingredient of toners for electrophotographic copies or printers, for home or office use.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The sealed toner cartridges and bottles containing the notified chemical will be imported to Australia by sea, stored at the notifier's warehouse, and transported by road or rail throughout Australia to distributors. Plastic cartridges or bottles containing 80 g to 2500 g of toner are packaged in corrugated cardboard outer boxes. The cartridges are also individually enclosed in a plastic bag.

5.2. Operation description
Cartridges or bottles of toner in powder form, containing < 2% of the notified chemical, will be used in printing and photocopying machines in offices and homes. The containers of toner will remain sealed until they are inserted in the machines.

5.3. Occupational exposure
Number and Category of Workers
Transport and storage workers should number in the tens and be exposed only in the event of accidental packaging breach or faulty packaging. Office workers may number in the thousands and spend approximately 10 minutes changing a cartridge or bottle perhaps once a month. Maintenance workers may number in the tens and are potentially exposed throughout their working day but would be exposed to a variety of toners so that the number of days in a year involving exposure to the notified chemical may be single digit or number in the tens.

Exposure Details
Office workers may be intermittently exposed to the notified chemical when replacing the spent cartridge or bottle, and during maintenance and cleaning of printers or photocopiers. Any workers involved in maintenance or repair of the machines 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/bottle and the printing and photocopier machines. Repair or 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 inside the machine.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The product is imported into Australia in its end-use containers, and will not undergo any further reformulation. Therefore, no environmental release is expected apart from that from accidental spills during transport or handling accidents.

RELEASE OF CHEMICAL FROM USE

Under normal use conditions, environmental release of the notified chemical from the cartridge is not expected. In the case of spills, it is expected that the notified chemical will be physically contained and either swept or vacuumed up and subsequently disposed of to landfill.

Once the notified chemical is applied to paper, the majority of the notified chemical is expected to remain fused to the paper or trapped within the print. Paper to which the notified chemical will be bound within the print will eventually be disposed of to landfill, be incinerated, or be recycled. In the case of the latter, the notified chemical may be released in effluent from the de-inking process.

Residues left in empty cartridges (estimated to be less than 1% total import volume) are expected to be recycled or reused along with all residual toner in the recycling process. Spent cartridges that are not recycled are expected to be disposed of to landfill.

5.5. Disposal

It is expected that the spent cartridges containing residual notified chemical will either be disposed of to landfill or be recycled. Notified chemical may also be disposed of indirectly from waste paper containing the notified chemical via recycling, to landfill or by incineration.

5.6. Public exposure

The public may be intermittently exposed to the notified chemical when replacing the spent cartridges or bottles of toner, and during any 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 inside the machine.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Black powder

Melting Point/Freezing Point Could not be determined

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Decomposes above 300ºC without melting.
TEST FACILITY	Huntingdon (2004a)

Boiling Point Could not be determined.

Remarks In a melting temperature test, the substance decomposed without melting.

Density Relative density D^{22}_4 1.40

METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method using a displacement liquid.
TEST FACILITY	Huntingdon (2004a)

Vapour Pressure 9.7×10^{-12} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks Vapour pressure balance method. 0.15 g was added to the furnace, the apparatus was assembled and evacuated to a pressure of less than $1X10^{-5}$ Torr. Initial runs were high and variable. These were considered to be due to degassing and/or removal of volatile impurities., and were thus disregarded. Two definitive tests were subsequently performed when the response had settled. With respect to the environment, the notified chemical is only very slightly volatile (Mensink *et al*, 1995).

TEST FACILITY Huntingdon (2004a)

Water Solubility <0.02 mg/L

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Column Elution Method was chosen on the basis of a preliminary visual test determining the solubility of the notified chemical to be less than 10 mg/L. This value was reported to be 0.13 mg/L in the aquatic toxicity tests. With respect to the environment, the notified chemical is only very slightly water soluble (Mensink *et al*, 1995).

TEST FACILITY Huntingdon (2004a)

Hydrolysis as a Function of pH Not determined

Remarks The hydrolysis was not determined due to the low water solubility of the notified chemical and the lack of a sufficiently sensitive substance-specific method of analysis. Two hydrolysable groups are present, but hydrolysis is not expected to occur in the environmental pH range (4-9) under ambient conditions due to the low water solubility.

TEST FACILITY Huntingdon (2004b)

Partition Coefficient (n-octanol/water) log Pow = >6.2 at 20°C

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks HPLC Method/Flask Method A limited test only was performed due to the high anticipated log Pow value. A solution of the notified chemical (0.1 g/L in mobile phase) was prepared and chromatographed alongside a sample of the reference substance DDT, which has a known log Pow value of 6.2.

TEST FACILITY Huntingdon (2004a)

Adsorption/Desorption log K_{oc}>5.6 at 25°C

METHOD OECD TG 121
EEC Method C19

Remarks HPLC Method. The notified chemical was found to elute after the six reference substances, including DDT with a known log Koc = 5.63.

TEST FACILITY Huntingdon (2004a)

Dissociation Constant Does not dissociate over the normal environmental pH range.

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Spectrophotometric method was used. The titration method was not suitable because of the low aqueous solubility. During dilution of the test substance, methanol was used as a cosolvent in order to maintain solubility. The pH of solutions tested were 4.1, 6.7 and 12.2

TEST FACILITY Huntingdon (2004a)

Particle Size

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

Range (μm)	*Mass (%)*
> 30	0
10.4 – 30	21.5
0.5 – 10.4	78.5

Remarks Initial test was by the sieve method. The main test was carried out by image analysis, using heavy distillate of petroleum as a suspending medium
TEST FACILITY Huntingdon (2004a)

Flammability - Solids Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks The test substance darkened whilst in contact with the ignition source, but did not melt or ignite.
TEST FACILITY Huntingdon (2004a)

Autoignition Temperature None below 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The temperature was increased by 0.5°C per minute.
TEST FACILITY Huntingdon (2004a)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks Tests for thermal sensitivity (effect of flame) and mechanical sensitivity (shock and friction) were performed.
TEST FACILITY Huntingdon (2004a)

Oxidising Properties Non-oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks Mixtures of the test substance and cellulose did not burn to completion.
TEST FACILITY Huntingdon (2004a)

Reactivity Stable under normal environmental conditions.

Remarks May form explosive dust/air mixtures when finely dispersed in air. Thermal decomposition products include oxides of carbon and nitrogen.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse local lymph node assay.	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test in human lymphocytes	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 96/54/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
EPA Health Effects Test Guidelines OPPTS 870.1100 Acute Oral Toxicity EPA 712-C-02-190. 2002.
Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, Acute oral toxicity (2-1-1), 12 Nohsan No 1847, Agricultural Production Bureau, November 24, 2000.

Species/Strain: Rat/Crl: CD: BR
Vehicle: Corn oil.
Remarks - Method: No deviations from protocol.

RESULTS

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

LD50: > 2000 mg/kg bw
Signs of Toxicity: Loose faeces and abnormal coloured faeces (red and/or black) were recorded for all animals from approx. 3 hours after dosing, with loose faeces resolving by day 2 and abnormal coloured faeces by day 3.
Effects in Organs: None.
Remarks - Results: None.

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

TEST FACILITY: HLS (2004c).

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notfied chemical.

METHOD: OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
EPA Health Effects Test Guidelines OPPTS 870.1200 Acute Dermal Toxicity EPA 712-C-98-192. August 1998.
Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, Acute dermal toxicity (2-1-2), 12 Nohsan No 1847, Agricultural Production Bureau, November 24, 2000.

Species/Strain: Rat/CD

Vehicle	Corn oil.
Type of dressing	Occlusive.
Remarks - Method	No protocol deviations.

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	Slight to well-defined erythema was noted in all animals on days 2 and 3, persisting until day 6 or 7 in four animals. Very slight oedema was noted in 2 animals on day 2, persisting until day 3 in one animal.
Signs of Toxicity - Systemic	None.
Effects in Organs	None.
Remarks - Results	None.

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

TEST FACILITY HLS (2004d).

7.3. Acute toxicity – inhalation

Study not conducted. The notified chemical is not expected to be volatile and inhalation exposure is limited as it is imported in cartridges at less than 2%.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
EPA Health Effects Test Guidelines OPPTS 870.2500 Acute Dermal Irritation EPA 712-C-98-196. August 1998.
Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, Skin irritation (2-1-4), 12 Nohsan No 1847, Agricultural Production Bureau, November 24, 2000.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Reverse osmosis water.
Observation Period	72 hours.
Type of Dressing	Semi-occlusive.
Remarks - Method	No protocol deviations.

RESULTS No erythema or oedema was noted at any time point (1, 24, 48 or 72 hours).

Remarks - Results Black staining interfered with scoring erythema.

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

TEST FACILITY HLS (2004e).

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
EPA Health Effects Test Guidelines OPPTS 870.2400 Acute Eye Irritation EPA 712-C-98-195. August 1998.
Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, Eye Irritation (2-1-5), 12 Nohsan No 1847, Agricultural Production Bureau, November 24, 2000.

Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 8 days.
Remarks - Method No protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	2	1	2	72 hours	0
Conjunctiva: chemosis	0	0	0	0		
Conjunctiva: discharge	0	0	0	0		
Corneal opacity	0	0	0	0		
Iridial inflammation	0	0	0	0		

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

Remarks - Results None.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY (HLS, 2004f).

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

TEST SUBSTANCE Notified chemical.

METHOD

Species/Strain Mouse/CBA/Ca
Vehicle 4:1 Acetone:olive oil
Remarks - Method No protocol deviations.

RESULTS

Concentration (% w/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	460.9	
5	545.7	1.2
10	1244.4	2.7
25	458.0	1.0
Positive Control (HCA)		
0	136.7	
10	208.4	1.5
25	478.6	3.5
50	800.5	5.9

Remarks - Results The positive control data was at the low end of the range of historical data.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	(HLS, 2004g).

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, Repeated Dose 28-Day Oral Toxicity Study in Rodents, July 2000.
Species/Strain	Rat/Crl:CD® (SD)IGS BR
Route of Administration	Oral – gavage/diet/drinking water
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None.
Vehicle	Corn oil.
Remarks - Method	Acclimatisation period was greater than 1 week and the Week –1 bodyweights and food consumption were recorded. During the first few days of the study, due to the thick nature of the dose at the high dose level, the catheter came away from the syringe on a few occasions resulting in a loss of dose remaining in the syringe. From day 5 onwards a larger bore catheter was used.

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

No signs of toxicological importance other than black staining of fur and faeces. Sensory reactivity and grip strength, motor activity, bodyweight gain, food consumption and food conversion efficiency were all generally similar to controls.

Laboratory Findings – Clinical Chemistry, Haematology

Clinical chemistry: Elevated alanine aminotransferase in high dose animals and elevated cholesterol in high dose females; elevated globulin in mid and high dose females. These were judged to be treatment related. Elevated urea in high dose males and lower urea in high dose females were judged to have occurred by chance.

Haematology: Elevated haemoglobin, haematocrit and red blood cell concentrations in high dose animals were, for the latter two parameters in the males, due mainly to the values for a single animal. High dose males also exhibited high group mean cell haemoglobin levels. Mid and high dose females exhibited a faster mean activated partial thromboplastin time. Elevated white blood cell counts for high dose females were due mainly to the results for a single animal.

Effects in Organs

High dose females exhibited higher liver and spleen weights (relative to body weight).

Pink discolouration of the forestomach epithelium was observed in 3/5 mid dose males and all high dose animals. Dark contents of the gastrointestinal tract due to the colour of the notified chemical was observed in most mid dose and all high dose animals.

High dose animals exhibited enlarged sinus histiocytes in the mesenteric lymph nodes. The mesenteric lymph nodes were darker in all high dose animals.

Generalised hepatocyte hypertrophy was seen in high dose females and centrilobular hepatocyte hypertrophy was seen in high dose males.

Remarks – Results
Haemoconcentration observed in high dose females and to a lesser extent high dose males is unexplained but may be related to elevated spleen weights in females.

The blood chemistry and microscopic examinations identified the liver as the target organ and the lack of necrosis suggested the changes were adaptive in nature.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on the absence of any evidence of overt toxicity.

TEST FACILITY HLS (2005).

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.
EPA Health Effects Test Guidelines OPPTS 870.5100 Bacterial reverse mutation test EPA 712-C-98-247.
Japanese Ministry of Agriculture, Forestry and Fisheries, Test Data for Registration of Agricultural Chemicals, 12 Nohsan No 1847, Agricultural Production Bureau, November 24, 2000.
Plate incorporation procedure and Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA (pKM101)
Metabolic Activation System	Microsomal fraction (S9) from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate b) Without metabolic activation: 0 - 5000 µg/plate
Vehicle	DMSO
Remarks - Method	No protocol deviations.

RESULTS

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

Remarks - Results Positive controls demonstrated the sensitivity of the test system and negative controls were within historical limits.

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

TEST FACILITY HLS (2004h).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Joint Directives of JEPA, JMHW and JMITI (31 October 1997)
JMHW Genotoxicity Testing Guideline, PAB Notification No. 1604 (1 November 1999)
US EPA (1998) Health Effects Test Guidelines. OPPTS 870.5375. *In vitro* Mammalian Chromosome Aberration Test. EPA 712-C-98-223.

Cell Type/Cell Line Human lymphocytes.
Metabolic Activation System Microsomal fraction (S9) from Aroclor 1254 induced rat liver.
Vehicle DMSO
Remarks - Method None.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	7.81*, 31.25*, 125*	3 hrs	19 hrs
Test 2	2.5*, 10*, 20*	19 hrs	19 hrs
Present			
Test 1	150*, 200*, 350*	3 hrs	19 hrs
Test 2	80*, 100*, 180*	3 hrs	19 hrs

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	125 (MI 47%)	Mitotic index reduced to ~ 50% at highest dose	Not noted	None
Test 2	50 (MI 37%)	"	Not noted	"
Present				
Test 1	350 (MI 52%)	"	Not noted	"
Test 2	200 (MI 53%)	"	Not noted	"

Remarks - Results None.

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

TEST FACILITY HLS (2004i).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
EC Directive 92/69/EEC C.4-E

Inoculum: Sewage Sludge
Exposure Period: 28 days
Auxiliary Solvent: None
Analytical Monitoring:
Remarks - Method: Eighteen bottles were filled with mineral salts medium inoculated with sewage effluent (1 mL/L) and the notified chemical was added at a nominal concentration of 4 mg/L. Four further bottles were established for a concurrent five-day microbial inhibition assay, in which the degradation of the readily degradable reference substance sodium benzoate was examined in the presence of the test substance. Groups of eighteen control and reference bottles were filled with inoculated mineral salts medium, with and without sodium benzoate (5 mg/L). The concentration of dissolved oxygen (DO) in duplicate bottles from each group were measured at the start of the test and after five days of incubation at 22 ± 2°C in darkness. DO concentrations in the control and reference groups and in bottles containing the notified chemical alone were also measured.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	3	5	77
7	6	7	83
11	2	11	83
14	0	14	82
18	5	18	71
21	3	21	77
25	2	25	89
28	0	28	87

Remarks - Results: The reference substance, sodium benzoate, was biodegraded to 77% of its theoretical value after five days of incubation and had achieved a maximum of 89% on Day 25 of the test. In the presence of the notified chemical, biodegradation of sodium benzoate had achieved 73% after five days. These results confirm that the inoculum was viable and that the test substance was not inhibitory to the activity of the microbial inoculum. Oxygen consumption by Day 28 in control bottles containing inoculated medium was acceptable for this assay system.

CONCLUSION: The notified chemical was found to be not readily biodegradable.

TEST FACILITY: Huntingdon (2004j)

8.1.2. Bioaccumulation

TEST SUBSTANCE: Notified chemical

CONCLUSION: It is considered that the notified chemical has the potential to bioaccumulate in the aquatic environment as the log Pow >6. In addition,

the substance is not ready biodegradable and is likely to persist in the environment. The value for log Koc of >5.6 suggests that the substance is immobile in the terrestrial environment. The low water solubility also indicates that the substance is not available to aquatic organisms.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD
- Species: Medaka (*Oryzias latipes*)
- Exposure Period: 96 hours
- Auxiliary Solvent: DMSO
- Water Hardness: 30-100 mg $CaCO_3$/L
- Analytical Monitoring: LC/MS
- Remarks – Method: Because the solubility in water of the notified chemical is 0.13 mg/L, the concentration of the definitive test was determined to be 0.13 mg/L or less. All test medium factors remained within the test guidelines.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	0	10	0	0	0	0	0
Solvent Control	0	10	0	0	0	0	0
0.130	0.119	10	0	0	0	0	0

- LC50: >0.119 mg/L at 96 hours.
- NOEC: 0.119 mg/L at 96 hours.
- Remarks – Results: The proportion of the measured concentration to the nominal values were 95% at the time of preparation and 86-88% after 24 h exposure.

CONCLUSION: The notified chemical was found not to be toxic to fish up to the limit of its water solubility.

TEST FACILITY: Mitsubishi (2005a)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE: Notified chemical

METHOD
- Species: *Daphnia magna*
- Exposure Period: 48 hours
- Auxiliary Solvent: DMSO
- Water Hardness: 250 mg $CaCO_3$/L
- Analytical Monitoring: LC/MS
- Remarks - Method: The concentration of the test was determined to be ≤0.13 mg/L which is the solubility of the notified chemical in water. The appearance of all test solutions were colourless. All test medium factors remained within the test guidelines. There were no recorded deviations from the test protocol.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<0.000005	20	0	0
Solvent Control	<0.000005	20	0	0
0.13	0.122	20	0	0

LC50 >0.0989 mg/L at 48 hours
NOEC 0.0989 mg/L at 48 hours
Remarks - Results The proportions of the measured concentrations to the nominal values were 94% at the time of preparation and 62% after 24 hours. The main cause that reduced the concentration is considered to be the adsorption to daphnids, because the concentration in test the solution without daphnids did not decrease in the preliminary test.

CONCLUSION The notified chemical was found not to be toxic to daphnids up to the limit of its water solubility.

TEST FACILITY Mitsubishi (2005b)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species *Pseudokirchneriella subcapitata*
Exposure Period 72 hours
Concentration Range Nominal: 0.130 mg/L
Actual: 0.129 mg/L
Auxiliary Solvent DMSO
Analytical Monitoring LC/MS
Remarks - Method Static, open (air-permeable) system, shake culture (100 rpm). The test medium was observed to be clear and colourless throughout the duration of the test. A control and solvent control test were run in conjunction with the single concentration test. All test medium factors remained within the test guidelines. There were no recorded deviations from the test guidelines.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
>0.129	0.129	>0.129	0.129

Remarks - Results The proportion of the measured concentration to the nominal value in test solution was 99% at the beginning of exposure but only 1% at the end of exposure. This was likely to be due to a chemical change in the test culture under the test conditions (4000 lux, 100 rpm), and/or adsorption to the algal cells.

CONCLUSION The notified chemical was found not to be toxic to algae up to the limit of its water solubility.

TEST FACILITY Mitsubishi (2005c)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge from Worlingworth (domestic) STP.
Exposure Period	3 hours
Concentration Range	Nominal: 1, 10, and 100 mg/L
Remarks – Method	The reference inhibitor 3,5-dichlorophenol (3,5-DCP) was employed at 3, 10 and 32 mg/L, as a positive control. The maximum temperature of the laboratory where the sample of activated sludge was maintained overnight under aerobic conditions was 22.5°C, which was slightly higher than the recommended maximum for this type of test (22°C). The measured temperature of the diluted sludge at 4 g/L on the day of the test (20.1°C) and the temperature of inoculated mixtures at the start of the test period (range, 19.6-19.9°C) were within the recommended temperature range for this type of test (20±2°C). This deviation was not considered to be significant nor to have affected the integrity of the test.
RESULTS	
IC50	>100 mg/L
NOEC	100 mg/L
Remarks – Results	The specific respiration rate of the control culture established at the start and the end of the test series was 24.2 $mgO_2/g/h$ and the three-hour 50% effect concentration (EC50) for 3,5-DCP was calculated to be 6.6 mg/L (95% confidence limits 4.5-9.5 mg/L). These results show that the test was valid and that the sample of activated sludge employed was sensitive to inhibition.
CONCLUSION	The notified chemical was considered to have had no biologically significant inhibitory effect on the respiration rate of activated sludge in the test.
TEST FACILITY	Huntingdon (2004k)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure of the notified chemical will result from the disposal of cartridges, printed-paper and any leaked toner containing the chemical during the use of the cartridges. The total import volume of the notified chemical will ultimately be either be disposed of to landfill, incinerated or recycled with paper.

The notified chemical is only very slightly volatile, and is therefore, not expected to dissipate into air from the paper. It is only very slightly water-soluble and is therefore, not expected to remain within the aquatic environment. It is expected to be poorly mobile in soil due to the low water solubility. The notified chemical is not readily biodegradable.

Incineration of waste paper and sludge will destroy the compound with the generation of water vapour and oxides of carbon. Recycling may take place in a number of centres throughout Australia. 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 ink and it is generally assumed at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. Only a small proportion can be expected to remain in the aqueous phase due to the low water solubility of the notified chemical.

A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where the entire import volume (the maximum of 3000 kg) of the notified chemical will be used on paper and 50% of the printed paper will be recycled with 10% of the chemical remaining in the aqueous phase during the recycling process. Under this scenario 150 kg of the notified chemical per year will be discharged to sewer and if assumed that none is attenuated within the sewage treatment plants (STP), the daily release on a nationwide basis to receiving waters is estimated to be 0.41 kg/day.

Based on 5% of the notified chemical being released to the sewer, a Predicted Environmental Concentration (PEC) in the aquatic compartment can be estimated, as shown below.

Amount released to sewer: 150 kg
Population of Australia: 20.1 Million
Water use per person per day: 200 L
Number of days used: 365
PEC_{Sewer}: $\frac{150,000,000,000}{365 \times 200 \times 20,100,000}$
= 0.07 µg/L
PEC_{River} (Dilution Factor = 1): 0.099 µg/L
PEC_{Ocean} (Dilution Factor = 10): 0.010 µg/L

Due to the low water solubility of the notified chemical, its potential for bioaccumulation is low in exposed aquatic organisms.

9.1.2. Environment – effects assessment

A predicted no effect concentration (PNEC - aquatic ecosystems) of 0.989 µg/L has been derived by dividing the end point value of 0.0989 mg/L (Green algae) by a safety factor of 100.

9.1.3. Environment – risk characterisation

	River	*Ocean*
PEC	0.099 µg/L	0.010 µg/L
PNEC	0.989 µg/L	0.989 µg/L
RQ (PEC/PNEC)	0.100	0.010

The worst case RQ values (PEC/PNEC) derived for the aquatic environment are very low and

well below 1 for both freshwater and marine waters, indicating no immediate concern to the aquatic compartment. Bioaccumulation is not expected from the diffuse use pattern and low import volume.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

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 or bottle, 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 bottles/cartridges and the low concentration of the notified chemical in the toner. Exposure will be minimised by placing photocopiers and printers in areas of adequate ventilation and the use of disposable gloves by service personnel.

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

9.2.2. Public health – exposure assessment

The public may be intermittently exposed to the notified chemical when replacing the spent cartridge or bottle, 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 bottles/cartridges and the low concentration of the notified chemical in the toner. 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 acute oral and dermal toxicity in rats (LD50 > 2000 mg/kg bw), was not a skin irritant and was a slight eye irritant in rabbits, was negative for sensitisation in a mouse LLNA test and was negative for in vitro mutagenicity in bacteria and clastogenicity in human lymphocytes.

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

The notified chemical is not likely to be hazardous to health on the basis of a full suite of toxicity tests for a standard notification. Exposure of office workers and maintenance personnel should be low and intermittent due to the design of the machines and the design of the cartridges or bottles to be inserted therein. Although typically toner can have a high proportion of particles near the respirable range, the notified chemical is at < 2% of the toner and the design of the cartridges and bottles should preclude significant exposure. The notified chemical is not identified as a safety hazard on the basis of physico-chemical properties. Therefore, the risk to occupational health and safety is judged to be low.

9.2.5. Public health – risk characterisation

The notified chemical is not likely to be hazardous to health on the basis of a full suite of toxicity tests for a standard notification. Exposure of the public should be low and intermittent due to the design of the machines and the design of the cartridges to be inserted therein. The notified chemical is not identified as a safety hazard on the basis of physico-chemical properties.

Therefore, the risk to public health and safety is judged to be low.

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

10.1. Hazard classification

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

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes. In relation to the environment the notified chemical may be classified as Chronic Category 4.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio of < 0.1, 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 proposed label for the notified toner 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

CONTROL MEASURES

Occupational Health and Safety

No special precautions are required for the notified chemical when used in a toner in pre-packed bottles or cartridges for 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 ventilated areas. The NOHSC Exposure Standard of 10 mg/m^3 TWA 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.

Disposal

- The notified chemical should be disposed of by incineration or to landfill

Emergency procedures

- Spills/release of the notified chemical should be swept up, placed in bag, and held for waste disposal.

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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