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September 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NT-6

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

NT-6

1. APPLICANT

Hewlett-Packard Australia Limited of 31-41 Joseph Street BLACKBURN VIC 3130 has submitted a standard notification statement in support of their application for an assessment certificate for NT-6.

2. IDENTITY OF THE CHEMICAL

For the notified chemical, NT-6, the following items of information are exempt from publication in the Full Public Report and the Summary Report.

Chemical name,
Other name,
CAS number,
Molecular and structural formulae,
Molecular weight,
Spectral data and
Non-hazardous impurities.

Trade Name: NT-6

NT-6 is considered to be hazardous based on the data provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

The below physico-chemical properties are for the notified chemical and not the toner to be imported.

Appearance: white powder with no odour.

Melting Point: 226 ± 0.5°C (decomposes before melting)

Specific Gravity: 2.0140 at 20.5 ± 0.5°C

Vapour Pressure:	1.3×10^{-4} Pa at 25°C (extrapolated)
Water Solubility:	12.7 mg/L at 20.0 ± 0.5°C (shake flask method)
Particle Size:	45-250 µm (majority of particles), < 10 µm (less than 2%)
Hydrolysis as a Function of pH:	< 10% after 5 days at 50°C at pH 4, 7 & 9 equates to: half-life > 1 year at 25°C at pH 4, 7 & 9
Partition Co-efficient (n-octanol/water):	$\log P_{ow}$ = 1.64 at 22.0 ± 0.5°C (average of three results, see comments below)
Adsorption/Desorption	K_{OC} = 7 320 in sandy loam, pH 4.8, oc 0.6% K_{OC} = 1 420 in sandy loam, pH 5.5, oc 1.8% K_{OC} = 472 in sandy loam, pH 7.3, oc 0.6%
Dissociation Constant:	pK_a = 4.69 at 21.0 ± 1.0°C
Flash Point:	not applicable
Flammability Limits:	not highly flammable
Autoignition Temperature:	311°C
Explosive Properties:	not explosive
Reactivity/Stability:	non-oxidising
Surface Tension:	72.6 mN/m at 20.0 ± 0.5°C

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. Full test reports were submitted.

The vapour pressure was determined by measurement at one temperature. This value was used to calculate the vapour pressure at 25°C using a theoretical model.

There was a slight decrease in the log partition coefficient (from 1.77 to 1.53) with the increasing n-octanol/water volume ratio (from 1:2 to 2:1).

Adsorption/desorption data show that the notified chemical ranges from immobile to moderately mobile, depending on the pH of the soil. The chemical's mobility increases with increasing pH.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (European Economic Community (EEC), 1992).

4. PURITY OF THE CHEMICAL

Degree of Purity: 86 - 94%

Hazardous Impurities: none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. NT-6 will be imported as a component (< 1%) of a fully formulated toner product ready for use in electrophoto-copying machines or electrophoto-graphic printers. The toner in sealed cartridges containing 300 grams of toner (< 3 g of notified polymer) will be mainly used by machines in office environments.

Annual import volumes for the notified polymer will be less than 1 tonne in the first five years.

6. OCCUPATIONAL EXPOSURE

Toner products containing the notified chemical will be imported in the form of pre-packed cartridges containing 300 g of toner. Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless packaging is breached.

Office workers may be exposed to the notified chemical during the operation and maintenance of photocopiers, facsimile machines and laser printers which use toner containing the notified chemical. The pre-packaged cartridges are sealed and workers are to use the replacement procedures recommended by the manufacturer. The toner cartridges are designed so that no release of the contents can occur until a shutter or seal tape is removed, however, dermal exposure may occur if toner containing the notified chemical is spilt while changing cartridges. Spent cartridges are expected to retain approximately 30 g of toner. While replenishing the toner in office equipment, the operator fits the cartridge to the machine and opens the shutter which allows transfer of the contents to storage within the machine. The majority particles

were of a size between 45 and 250 µm, however, approximately < 2% of particles are less than 10 µm in diameter, that is, approximating the respirable range of 0 to 7 µm (National Occupational Health and Safety Commission, 1995). Particle size data on the product has not been provided, however, the formulated toner product contains less than 1% of the notified chemical. During the printing process, the notified chemical will be fixed to the paper as part of the toner product.

Office equipment repair personnel have the potential to come into contact with the notified chemical more often than office workers, although exposures are still expected to be controlled, due to the design of the toner cartridges.

7. PUBLIC EXPOSURE

The toner containing the notified chemical will be imported in sealed cartridges. If accidental spillage occurs the notified substance can be swept up and disposed to incineration or landfill in accordance with local regulations. Waste toner can be disposed of similarly. No public exposure to the notified chemical is expected to occur in normal circumstances during transport.

Office staff with will replace spent cartridges in electrophotographic printers when necessary. The cartridge is designed so that it will not release its contents until the seal tape is removed. Throughout the printing operation, toner powder will not be accessible to the operator. The public may be exposed to residues of the notified chemical on photocopied paper; however, given that toner will be firmly fixed to the paper by heat, such exposure is expected to be minimal.

8. ENVIRONMENTAL EXPOSURE

Release

The toner (with the notified chemical) will be fused to the paper in a water insoluble matrix during printing. This use offers little potential for release into the environment, other than through the disposal of waste paper. When the printer requires more toner, the cartridge is replaced. The exchange process is designed to minimise toner losses.

The majority of the notified chemical will be associated with the fused toner and will be strongly bound to the paper. Its release will be associated with the fate of the waste paper.

Empty cartridges are normally expected to be disposed of with general office waste and placed into landfill. However, the notifier has in place a toner cartridge recycling/reuse program. Collected cartridges are to be shipped overseas. However, should cartridges be disposed of to landfill, release of toner, albeit minimal, will only occur after destruction of the integrity of the cartridge. The notifier has estimated the amount of toner in the cartridge when it is replaced to be approximately 30 g, or 0.3 g of notified chemical.

Fate

Waste paper disposal is effected either through incineration, recycling or deposition into landfill. Incineration will destroy the chemical with evolution of oxides of carbon and nitrogen, aluminium salts and water vapour.

The notifier has provided no data on the likely behaviour of the chemical during the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. It is expected that during the repulping and bleaching procedures employed during paper recycling, the chemical will be either destroyed chemically or be incorporated into waste sludge. However, as the chemical has appreciable water solubility, some may remain with aqueous waste streams generated during recycling. Waste sludge from the recycling plants will be either incinerated or disposed of to landfill, while aqueous waste should be comprehensively treated prior to discharge.

Some waste paper may be disposed of directly to landfill, and although only slowly hydrolysable and not readily bio-degradable (see below), it is anticipated that prolonged residence in an active landfill environment will eventually degrade the notified substance.

The notified chemical was found to exhibit 0% degradation after 28 days in the OECD Test 301B for 'Ready Biodegradability' (CO_2 Evolution Test). Therefore, the chemical can not be considered to be biodegradable under the strict terms of this test. The notified chemical was found not to inhibit the respiration of sewage sludge micro-organisms at the concentration employed in this test.

Bioaccumulation of the notified chemical is not expected due to its low log P_{OW} of 1.64 (Connell, 1989). Also, biological membranes are not permeable to chemicals of very large molecular size (Anliker et al., 1988).

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data was supplied for the notified chemical, NT-6, and for the toner (#1015 and #789) to be imported as indicated in this section.

9.1 Acute Toxicity

Summary of the acute toxicity of NT-6

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} = 334 mg/kg in males	(Allen, 1995a)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(Allen, 1995b)
skin irritation	rabbit	slight irritant	(Allen, 1995c)
eye irritation	rabbit	slight irritant	(Allen, 1995d)
skin sensitisation	guinea pig	non-sensitiser	(Allen, 1995e)

Summary of the acute toxicity of toner containing NT-6 (#1015 & #789)

Test	*Species*	*Material*	*Outcome*	*Reference*
acute oral toxicity	rat	#1015	LD_{50} > 5 000 mg/kg	(Allen, 1996a)
		#789	LD_{50} > 5 000 mg/kg	(Allen, 1995f)
skin irritation	rabbit	#1015	slight irritant	(Allen, 1996b)
		#789	slight irritant	(Allen, 1995g)
eye irritation	rabbit	#1015	slight irritant	(Allen, 1996c)
		#789	slight irritant	(Allen, 1995h)

9.1.1 Oral Toxicity

9.1.1.1 NT-6 (Allen, 1995a)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5 males/ dose group (0, 100, 224 and 500 mg/kg) and 5 females given 100 mg/kg
Observation period:	14 days
Method of administration:	gavage; vehicle: arachis oil
Clinical observations:	common signs of toxicity noted in males treated with 100 or 500 mg/kg were ataxia, decreased respiratory rate and laboured respiration with additional signs of lethargy; frequent signs of hunched posture with additional signs of splayed

	gait were also noted in males treated with 100 mg/kg; loss of righting reflex was commonly noted in males treated with 500 mg/kg; males treated with 100 mg/kg recovered one or two days after dosing; females treated with 100 mg/kg and males treated with 224 mg/kg appeared normal throughout the study; all surviving animals showed expected bodyweight gain during the study
Mortality:	all animals treated with 500 mg/kg were dead 2 - 4 hours after dosing
Morphological findings:	in males treated with 500 mg/kg that died during the study: haemorrhagic lungs, dark liver and dark kidneys
Test method:	according to OECD TG 401 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
LD_{50}:	334 mg/kg in males
Result:	the notified chemical exhibited moderate acute oral toxicity in rats

9.1.1.2 Toner containing NT-6 (#1015) (Allen, 1996a)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5 males/5 females
Observation period:	14 days
Method of administration:	gavage; vehicle: arachis oil
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	limit test, similar to OECD TG 401 (Organisation for Economic Co-operation and Development, 1995-1996)

LD_{50}:	> 5 000 mg/kg
Result:	toner containing the notified chemical (#1015) exhibited low acute oral toxicity in rats

9.1.1.3 Toner containing NT-6 (#789) (Allen, 1995f)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5 males/5 females
Observation period:	14 days
Method of administration:	gavage; vehicle: arachis oil
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	limit test, based on the OECD TG 401 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 5 000 mg/kg
Result:	toner containing the notified chemical (#789) exhibited low acute oral toxicity in rats

9.1.2 Dermal Toxicity (NT-6) (Allen, 1995b)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	test material was applied to a shorn area moistened with arachis oil and covered with a semi-occlusive dressing for 24 hours

Clinical observations:	no signs of systemic toxicity
Mortality:	no deaths
Morphological findings:	no abnormalities noted at necropsy and no signs of skin irritation
Test method:	limit test, according to OECD TG 402 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Skin Irritation

9.1.3.1 NT-6 (Allen, 1995c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	0.5 g of the notified chemical moistened with 0.6 mL of distilled water under semi-occlusive gauze dressing for 4 hours
Test method:	according to OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	observations at 1 hour, 1, 2 and 3 days after patch removal revealed that no animal exhibited oedema; 2 animals at 1 hour and 1 animal at 24 hours exhibited slight erythema; the notified chemical was a slight skin irritant in rabbits

9.1.3.2 Toner containing NT-6 (#1015) (Allen, 1996b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males; 1 female
Observation period:	72 hours
Method of administration:	0.5 g of the notified chemical moistened with 0.5 mL of distilled water under semi-occlusive gauze dressing for 4 hours
Test method:	according to OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	observations at 1 hour, 1, 2 and 3 days after patch removal revealed that no animal exhibited oedema; 2 animals at 1 hour and 1 animal at 24 hours exhibited slight erythema; toner containing the notified chemical (#1015) was a slight skin irritant in rabbits

9.1.3.2 Toner containing NT-6 (#789) (Allen, 1995g)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males; 1 female
Observation period:	7 days
Method of administration:	0.5 g of the notified chemical moistened with 0.5 mL of distilled water under semi-occlusive gauze dressing for 4 hours
Test method:	according to OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	observations at 1 hour, 1, 2, 3 and 7 days after patch removal revealed that no animal exhibited oedema; 1 animal at 1 hour, 2 animals at 24 and 48 hours and 1 animal at 72 hours exhibited slight erythema; toner containing the notified chemical (#789) was a slight skin irritant in rabbits

9.1.4 Eye Irritation

9.1.4.1 NT-6 (Allen, 1995d)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	72 hours
Method of administration:	0.1 mL (vehicle unspecified) of the notified chemical was placed into the conjunctival sac of the right eye of each animal
Test method:	according to OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	no corneal or iridal effects were seen; slight conjunctival redness was seen at 1 and 24 hours in 2 animals and at 1 hour in the third animal; slight chemosis was seen in 1 animal 1 hour post-instillation and slight discharge in another animal at the same time point the notified chemical was a slight eye irritant in rabbits

9.1.4.2 Toner containing NT-6 (#1015) (Allen, 1996c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	72 hours
Method of administration:	0.1 mL (vehicle unspecified) of the notified chemical was placed into the conjunctival sac of the right eye of each animal
Test method:	according to OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)

Result:	no corneal or iridal effects were seen; slight conjunctival redness was seen at 1 hour in all animals; slight chemosis was seen in 1 animal 1 hour post-instillation and slight discharge in another animal at the same time point toner containing the notified chemical (#1015) was a slight eye irritant in rabbits

9.1.4.3 Toner containing NT-6 (#789) (Allen, 1995h)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	72 hours
Method of administration:	0.1 mL (vehicle unspecified) of the notified chemical was placed into the conjunctival sac of the right eye of each animal
Test method:	according to OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	no corneal effects were seen; slight iridal effects were seen in 1 animal; slight conjunctival redness was seen at 1 hour in 2 animals; slight chemosis and discharge was seen in 1 animal 1 hour post-instillation toner containing the notified chemical (#789) was a slight eye irritant in rabbits

9.1.5 Skin Sensitisation (NT-6) (Allen, 1995e)

Species/strain:	guinea pig/Dunkin Hartley
Number of animals:	20 test and 10 control male animals
Induction procedure:	***day 0:*** intradermal induction by 3 pairs of injections of 0.1 mL consisting of:

- Freund's Complete Adjuvant (FCA) in distilled water (1:1);
- a 5% suspension of the notified chemical in arachis oil;
- a 5% emulsion of the notified chemical in a 1:1 preparation of FCA and distilled water

day 7:
occlusive dressing containing 25% notified chemical in arachis oil for 48 hours

Challenge procedure:

day 21:
10% and 25% notified chemical in arachis oil under occlusive dressing for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
10%	0/20**	0/20	0/10	0/10
25%	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD TG 406 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)

Result: the notified chemical was not a skin sensitiser in guinea pigs at the concentrations tested

9.2 Repeated Dose Toxicity (NT-6) (Coles et al., 1995)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 5/sex/dose

Method of administration: oral (gavage), vehicle: arachis oil

Dose/Study duration:: 0, 15, 50 or 150 mg/kg/day (control, low, mid or high dose, respectively) for 28 days

Clinical observations:	transient increased salivation after day 9 in the high dose group; no effects on bodyweight or food consumption
Clinical chemistry/Haematology:	no treatment-related changes observed; some individual high dose males exhibited reductions in total plasma protein, albumin and an increase in bilirubin but the group means were not significantly different; some non-dose-related effects observed were increased alanine aminotransferase levels in low dose males, increased urea in mid dose females and a reduction in blood glucose for low and mid dose females a slight increase in leukocyte count in high dose males and a decrease in clotting time in mid dose females were judged by the study authors not to be of toxicological significance
Necropsy findings/ Histopathology:	high dose males exhibited increased liver weights and one male exhibited a substantially elevated kidney weight; seven high dose animals showed dark livers and one male exhibited enlarged kidneys with a granular appearance no microscopic abnormalities were detected
Test method:	according to OECD TG 407 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 67/548/EEC (European Economic Community, 1992)
Result:	based on minor toxicologically significant changes in the liver at a dose level of 150 mg/kg/day, the NOEL is 50 mg/kg/day.

9.3 Genotoxicity (NT-6)

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Thompson, 1995)

Strains:	TA 1535, TA 1537, TA 1538, TA 98 and TA 100
Concentration range:	50 - 5 000 µg/plate

Test method:	according to OECD TG 471 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)
Result:	the notified chemical was not found to be mutagenic in *S. typhimurium* in the presence or absence of an exogenous metabolising system (rat liver S9 fraction)

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Durward, 1996)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/time point
Doses:	250 mg/kg; bone marrow sampled at 24, 48 and 72 hours
Method of administration:	intraperitoneal
Test method:	OECD TG 474 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	no significant increase in micronucleated polychromatic erythrocytes compared to controls; premature deaths in the 48 and 72 hour dose groups indicated systemic absorption

9.3.3 Chromosomal Aberrations in human lymphocytes *in* vitro (Wright, 1996)

Doses:	***experiment 1*** 20 hour incubation in 0, 4.88 (-S9), 9.75, 19.5 and 39 (+S9) µg/mL ***experiment 2*** 20 hour incubation in 0, 10, 20, 30, 40 µg/mL (-S9) and 0, 20, 40, 60 µg/mL (+S9) 44 hour incubation in 0, 30, 40 (+S9) µg/mL
Test method:	according to OECD TG 473 (Organisation for Economic Co-operation and Development, 1995-1996) and Commission Directive 92/69/EEC (European Economic Community, 1992)

Result:	no significant increase in the frequency of cells with chromosomal aberrations or polyploid cells in either the presence or absence of an exogenous metabolising system (rat liver S9 fraction)

9.4 Overall Assessment of Toxicological Data

The notified chemical was of moderate acute oral toxicity in rats (LD_{50} = 334 mg/kg in rats) and low acute dermal toxicity in rats (LD_{50} > 2 000 mg/kg). It was a slight skin and eye irritant in rabbits and was not a skin sensitiser in guinea pigs. Repeated oral dosing for 28 days resulted in hepatic changes at 150 mg/kg/day with a NOEL of 50 mg/kg/day. The notified chemical was not mutagenic in *S. typhimurium* in the presence or absence of metabolic activation, was not clastogenic in the mouse micronucleus assay, and did not induce chromosomal aberrations in human lymphocytes.

Two batches of toner (#1015 and #789) containing the notified chemical were of low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg) and were slight skin and eye irritants in rabbits.

The notified chemical is classified as hazardous (Harmful, R22) according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) in relation to acute lethal effects (oral route) but not in relation to the other toxicological data supplied. The toner containing the notified chemical would not be classified as hazardous, on the basis of either the amount of notified chemical percentage (1%, below the cut-off concentration of 25%) or the limited toxicological dataset provided for assessment.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data is normally required for chemicals with import volumes < 1 tonne per year according to the Act. However, ecotoxicity studies were provided by the notifier for the notified chemical (NT-6) and for the toner product and assessed.

Table 1: Ecotoxicity Test Results - Notified Chemical (NT-6)

Test	Species	Results (Actual)
Acute Toxicity - Semi-static [(a)] (OECD TG: 203)	Rainbow Trout (*Oncorhynchus mykiss*)	96 hr LC_{50} 0.95 mg/L NOEC 0.40 mg/L
Acute Toxicity (Immobilisation) - Static [(a)] (OECD TG: 202)	Water flea (*Daphnia magna*)	48 hr EC_{50} 0.79 mg/L NOEC 0.40 mg/L
Acute Toxicity (Reproduction) - Semi-static [(a)] (OECD TG: 202)	Water flea (*Daphnia magna*)	<u>Immobilisation</u> 21 day EC_{50} 0.47 mg/L LOEC 0.25 mg/L NOEC 0.080 mg/L <u>Reproduction</u> NOEC 0.25 mg/L
Inhibition - Biomass (B) and Growth Rate (μ) (OECD TG: 201)	Algae (*Scenedesmus subspicatus*)	72 hr E_BC_{50} > 4.0 mg/L [(b)] 24 hr $E_\mu C_{50}$ > 4.0 mg/L NOEC > 4.0 mg/L

(a) The test material was prepared using a preliminary solution in 9% v/v Tween 80-tetrahydrofuran.
(b) 4.0 mg/L was the highest attainable test concentration that could be prepared due to limited solubility in water and auxiliary solvent (9% v/v Tween 80-tetrahydrofuran).

Table 2: Ecotoxicity Test Results - Toner Containing Notified Chemical

Test	Species	Results (Actual)
Acute Toxicity - Semi-static (OECD TG: 203)	Rainbow Trout (*Oncorhynchus mykiss*)	96 hr LC_{50} > 1.0 mg/L [(a)] NOEC ≥ 1.0 mg/L
Acute Toxicity (Immobilisation) - Static (OECD TG: 202)	Water flea (*Daphnia magna*)	48 hr EC_{50} > 1.0 mg/L [(a)] NOEC ≥ 1.0 mg/L

(a) The test material was prepared using a preliminary solution in dimethylformamide. 1.0 mg/L was the maximum attainable test concentration.

The ecotoxicity data show the notified chemical to be highly toxic to both the rainbow trout and water flea. Fish deaths were first recorded at 1.3 mg/L at 48 hours, with behavioural responses first noted at 0.70 mg/L at 72 hours (*ie* increased pigmentation). Immobilisation of water fleas was first noted at 0.70 mg/L at 24 hours, with 100% immobilisation noted at 2.2 mg/L at 24 hours.

In the 21 day water flea study, mortality of a significant number of water fleas occurred in the 0.25 mg/L test group (23% immobilisation). This indicates that there is a prolonged toxic effect to water fleas to the notified chemical. At 21 days there were no statistically significant differences between the controls and test groups (number of young produced per

adult) up to 0.25 mg/L. Exposure to the notified chemical at 0.80 mg/L resulted in significant impairment of reproduction.

Algae inhibition tests show that the chemical can be classed as non-toxic up to the limits of its solubility. Neither the growth rate (μ) or biomass (b) of the algae were affected by the presence of 4.0 mg/L of the test material over the 72 hour exposure period.

The toner (containing the notified chemical at a concentration < 1%) can be classed as non-toxic to the rainbow trout and water flea up to the limits of its solubility (1.0 mg/L).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of notified chemical should not enter the environment until it is incorporated into a polymer matrix when the toner is cured and fixed to paper. Disposal of the waste paper containing the cured toner is normally through landfill, incineration or recycling. In all three cases it is anticipated that the chemical will be destroyed either through the agency of a vigorous chemical environment, or through (admittedly slow) biological or abiotic processes. Even in the absence of substantial degradation, the diffuse nature of disposal patterns would indicate slow release into the wider environment.

Accidental spillage of the toner, e.g. during transport, should result in powder wastes being sent to either landfill or incineration facilities. Empty cartridges containing small volumes of toner will either be collected and recycled overseas, or be sent to landfill or for incineration.

Due to the chemical's moderate water solubility and expected mobility in soils, movement of the chemical from landfill is possible and therefore could present an environmental hazard. However, the amount of notified chemical sent to landfill is likely to be minimal, with the majority contained within the toner cartridges, and disposed of to landfills throughout Australia. Any notified chemical leaching from landfills and entering the aquatic compartment is likely to be diffuse and at concentrations not likely to pose significant environmental effects.

Considering the above, the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the toxicological data supplied, the notified chemical is moderately toxic by the oral route and is classified as hazardous substance (harmful at cut-off concentrations ≥ 25%) according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). Since the notified chemical is to be imported at a concentration of less than 1% in toner, the toner itself would not be classified as hazardous with respect to NT-6. In addition, the limited toxicological dateset for the toner, namely acute oral toxicity and skin and eye irritation, do not suggest that the toner product is

a hazardous product.

Occupational exposure may occur during replacement of toner in photocopy machines. The use of tape-sealed cartridges will limit exposure unless the cartridge contents are spilt after the tape is removed. Higher exposure may occur during maintenance of photocopying equipment, however it is very unlikely that the exposure standard for nuisance dust (10 mg/m^3, inspirable) will ever be attained. The particle size distribution of the notified chemical indicates that only a very small proportion (< 2% below 10 µm diameter) would be respirable. The toner and toner products are slight skin and eye irritants. The event of minor skin or respiratory tract contamination after handling the cartridge in normal use is unlikely to cause any topical or systemic health effects. In the event of a large spill of toner from a cartridge, it would be appropriate for individuals to wear standard protective equipment because of the possibility of eye, skin and respiratory irritation.

The public and workers will make contact with the notified substance on photocopied paper; however, as the substance is bound to the paper, the amount of exposure and risk will be minimal.

The risk of adverse health effects to workers or the public arising from the transport, storage, use or disposal of the notified chemical is expected to be negligible

13. MATERIAL SAFETY DATA SHEET

The MSDS for the toner containing the notified chemical was provided in a format similar to that specified by the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994c).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

14. RECOMMENDATIONS

To minimise occupational exposure to NT-6 the following guidelines and precautions should be observed:

- Work areas around printers should be well ventilated and good work practices should be implemented to avoid the generation of dusts; such as taking care to avoid contact with the toner adhering to the plastic tape which seals the cartridge and if contact occurs removing toner immediately by washing.

- Spillage of toner products should be avoided and good personnel hygiene should be practiced to minimise the potential for ingestion.

- A copy of the MSDS and/or information about the toners containing NT-6 should be easily accessible to employees.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Allen D (1995a) #868: Acute oral toxicity test in the rat, Project No. 480/090, Safepharm Laboratories, Derby, UK.

Allen D (1995b) #868: Acute dermal toxicity (limit test) in the rat, Project No. 480/091, Safepharm Laboratories, Derby, UK.

Allen D (1995c) #868: Acute dermal irritation test in the rabbit, Project No. 480/092, Safepharm Laboratories, Derby, UK.

Allen D (1995d) #868: Acute eye irritation test in the rabbit, Project No. 480/093, Safepharm Laboratories, Derby, UK.

Allen D (1995e) #868: Magnusson & Kligman maximisation study in the guinea pig, Project No. 480/094, Safepharm Laboratories, Derby UK.

Allen D (1995f) #789: Acute oral toxicity (limit test) in the rat, Project No. 480/32, Safepharm Laboratories, Derby, UK.

Allen D (1995g) #789: Acute dermal irritation test in the rabbit, Project No. 480/33, Safepharm Laboratories, Derby, UK.

Allen D (1995h) #789: Acute eye irritation test in the rabbit, Project No. 480/34, Safepharm Laboratories, Derby, UK.

Allen D (1996a) #1015: Acute oral toxicity (lmit test) in the rat, Project No. 480/170, Safepharm Laboratories, Derby, UK.

Allen D (1996b) #1015: Acute dermal irritation test in the rabbit, Project No. 480/171, Safepharm Laboratories, Derby, UK.

Allen D (1996c) #1015: Acute eye irritation test in the rabbit, Project No. 480/172, Safepharm Laboratories, Derby, UK.

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European Economic Community (EEC) (1992) EEC Directive 92/69. Methods for the determination of physico-chemical properties.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994b) Control of Workplace Hazardous Substances [NOHSC:1005(1994), 2007(1994)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994c) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

Organisation for Economic Co-operation and Development (1995-1996) OECD Guidelines for the Testing of Chemicals on CD-Rom. Paris, OECD.

Thompson P (1995) #868: Reverse mutation in the Ames Test using Salmonella typhimurium, Project No. 480/096, Safepharm Laboratories, Derby, UK.

Wright, NP (1996) #868: Chromosome aberration test in human lymphocytes in vitro, Project No. 480/097, Safepharm Laboratories, Derby, UK

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe