File No: NA/937

October 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

NT-20

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

NT-20

1. APPLICANT

Canon Australia Pty Ltd (ACN 005 002 951) of 1 Thomas Holt Drive, North Ryde Sydney NSW 2113 and HP Australia Ltd. (ABN 95 767 533 621) of 31-41 Joseph Street Blackburn, Victoria 3130 have submitted a limited notification statement in support of their application for an assessment certificate for NT-20.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name:	NT-20
Method of Detection and Determination:	ultraviolet-visible (UV-Vis), infrared (IR) and nuclear magnetic resonance (NMR) spectroscopy.
Spectral Data:	UV-Vis, IR and NMR spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Magenta powder
Melting Point:	Not determinable. Decomposed on melting at 330.0 to 332.5°C (see below).
Specific Gravity:	1.38 at 21°C
Vapour Pressure:	5×10^{-12} kPa at 25°C
Water Solubility:	< 0.1 mg/L
Particle size:	7% < 10 micron 20.4% 10.4 – 30 micron 25.3% 30 – 60 micron 22.9% 60 – 105 micron 24.7% > 105 micron

Partition Co-efficient (n-octanol/water):	log Pow = 4.2
Hydrolysis as a Function of pH:	Not determined (see comments below).
Adsorption/Desorption:	log Koc : > 5.4
Dissociation Constant:	Not determined (see comments below).
Flash Point:	Not applicable for solid
Flammability Limits:	Not highly flammable
Autoignition Temperature:	Relative self-ignition temperature: not below 400°C
Explosive Properties:	Not explosive
Reactivity/Stability:	Oxidizing properties: non-oxidizing

3.1 Comments on Physico-Chemical Properties

Melting point was determined in accordance with OECD Method 102 (EEC Method A1) using the metal block method. The boiling point was unable to be determined because the notified chemical decomposed upon melting.

Relative density was determined in accordance with OECD Method 109 (EC Method A3) using a pycnometer at 21°C.

Vapour pressure was determined in accordance with OECD Method 104 (EC Method A4) using a vapour pressure balance. The notified chemical is regarded as very slightly volatile (Mensink, 1995).

Water solubility was determined in accordance with OECD Method 105 (EC Method A6) using the flask method and is considered to be practically insoluble.

The extent of hydrolysis was unable to be determined because of the low water solubility of the notified chemical. However, no functional groups are expected to hydrolyse in the environmental pH range of 4-9.

The partition coefficient was determined in accordance with OECD Method 117 (EC Method A8) using HPLC. The notified chemical is considered to be hydrophobic and will preferentially partition into the organic phase.

Adsorption/desorption was determined in accordance with OECD Draft Method 121 using HPLC. The high nominal log Koc value indicates that the chemical will associate with soils and sediments and will not readily leach.

The dissociation constant was not determined because of the low water solubility.

4. PURITY OF THE CHEMICAL

Degree of Purity: 98.5 %

Hazardous Impurities: None

Non-hazardous Impurities (> 1% by weight): 1.5%

Additives/Adjuvants: None

Weight Percentage of toner Ingredients:

Ingredient	*Weight %*
NT-20	1-5 %
binder resin(s)	70-90 %
wax	5-15 %

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a toner ingredient (1 - 5 % by weight) for use in electro-photocopying machines and electro-photographic printers. It will not be manufactured or reformulated in Australia but will be imported in bottles of 2 - 4 L capacity or cartridges at 1 - 7 L capacity as a ready-to-use consumer product. The toner bottle or cartridge is designed so that it will not release the contents until the shutter or seal is removed. The toner will then be transferred to paper and fixed during the copy or printing operation.

The import volume will be less than 1 tonne/year for the first five years.

6. OCCUPATIONAL EXPOSURE

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

Office workers and machine maintenance workers may be intermittently exposed to the notified chemical contained in the toner cartridge or bottle when replacing the spent container, and during repair maintenance and cleaning of printers or photocopiers. Maintenance workers for printers or photocopiers may potentially come in contact with the notified chemical more often than office workers. Exposure is expected to be controlled through the design of the cartridges or bottles and the printing or photocopying machines. Printer or photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed cartridges or bottles are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer.

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

7. PUBLIC EXPOSURE

The transport of the bottles or cartridges should not present any risk of public exposure to the notified chemical. Cartridges and bottles are however, in widespread use in work sites and in the home office. There are also many people involved in the disposal and recycling of these devices and in the disposal and recycling of printed paper. Thus the potential for contact with toner once the shutter or seal is removed increases markedly.

During use the toner bottle or cartridge is installed inside the photocopying or printing machine. During copying or printing the toner will be transferred to the paper and firmly fixed to it by heat. There may be some accidental spillage of toner onto the hands of the user during removal of the shutter or sealing tape or during placement of the bottle or cartridge into the copier or printer. It is possible that the hands of users may be infrequently but repeatedly exposed to toner dust. Serious spills may also present the opportunity for the fine toner dust to enter the eyes or be inhaled, however, such spills are likely to be very rare.

Spilt powder is to be placed onto paper and transferred to a sealable waste container. The remainder is to be cleaned with wet paper, wet cloth or a vacuum cleaner with a dust explosion-proof rating.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Emissions into the hydrosphere can occur at different phases of the life cycle of a substance used in the printing and publishing industry. The life cycle begins with the production and formulation of the toner product followed by the processing cycle and ends with the recovery and discharge into waste water or waste (Baumann *et al*., 1999).

Transport
Losses during this process will be minimal as the notified chemical is housed in sealed bottles or cartridges designed to prevent release of the toner until the shutter or sealing tape is removed. Accidental spillage of the toner, either during transport should result in powder wastes being sent to either landfill or incineration facilities.

End User Site
Losses are expected to be negligible because the storage bottles and cartridges will remain sealed until they are placed inside photocopiers or printers. Under normal use, the toner is transferred onto a sheet of paper where it is firmly fixed to the surface by heat. The notified chemical will be fixed into the cured toner and there will be limited release to the environment. Accidental spillage of the toner during replacement of cartridges and bottles should result in powder wastes being sent either to landfill or to incineration facilities. Where a toner bottle is used, additional release to the environment will result from the disposal of the used toner container from the photocopy machine.

The used toner container collects toner within the machine that does not become attached to paper. The amount of the notified chemical in used toner could be as high as 50 kg/year, given that the maximum loss can be estimated at 5% and the maximum yearly import volume is 1 tonne. In the case of cartridges, the used toner remains in the cartridge.

Recycling and Disposal
The majority of the notified chemical entering the environment will be fused to paper. The waste paper generated will be disposed through landfill, recycling, or incineration. Current paper recycling rates in Australia are estimated at 70-92 % (Australian Environmental Review, 2001). In landfill, the toner (and thus the notified chemical) should remain fixed to the paper substrate and remain immobile.

Spent cartridges and bottles that are not recycled are likely to be sent to landfill. As a worst case, a maximum of 150 kg/year of the uncured notified chemical could be sent to landfill from this route if maximum import quantities are assumed and a maximum loss of 15% from each bottle or cartridge is anticipated. The disposal of cartridges, bottles and used toner containers would be widespread across Australia.

8.2 Fate

Some waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified chemical. Incineration of the waste paper will destroy the notified chemical with the generation of water vapours and oxides of carbon and nitrogen.

When the paper is recycled, waste sludge containing the notified chemical will be disposed of to landfill. It is estimated that the removal of ink particles during the de-inking phase of paper recycling is 30-60% efficient for xerographic copying. It is likely that the same proportion of notified chemical retained in the paper fibre will remain in the sludge when the waste paper is re-pulped. Recycling is carried out in paper mills where it is likely that at least primary sedimentation is carried out. It can be assumed that nearly 100% of easily soluble substances will be released to waste water after primary treatment while around 50% of poorly soluble substances will be removed to sludge (EC, 1994). Sludges produced by flotation and clarification will be de-watered and disposed of to landfill. It is likely that the bulk of the notified chemical will remain bound to the sludge in landfill and will not mobilise to groundwater, given the high adsorption/desorption value and low water solubility (Gustafson, 1989). Incinerated toner wastes will generate water and some oxides of carbon and nitrogen.

No test results for degradation of the notified chemical were submitted, but it is expected to slowly degrade in landfill. There is potential for bioaccumulation, given the low water solubility and high log Pow, but this will be low because of the proposed use pattern and the limited exposure to the aquatic compartment.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data were collected on NT-20 - the notified chemical or ST383 – the notified chemical plus a 10% additive (identity is exempt information).

9.1 Acute Toxicity

Summary of the acute toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity (ST383)	rat	LD50 > 2000 mg/kg	(Safepharm Laboratories, 2000a).
skin irritation (ST383)	rabbits	non-irritant	(Safepharm Laboratories, 2000b).
eye irritation (ST383)	rabbit	slightly irritating	(Safepharm Laboratories, 2000c).
skin sensitisation (NT-20)	guinea pig	non-sensitiser	(Huntington Life Sciences Ltd, 2001a)
(ST383)	mouse	non-sensitiser	(Huntington Life Sciences Ltd, 2000)

9.1.1 Oral Toxicity, ST383 (Safepharm Laboratories, 2000a).

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	3/sex
Observation period:	Up to fourteen days.
Method of administration:	2000 mg/kg, delivered orally, by gavage in a suspension in arachis oil BP.
Test method:	OECD TG 423; Directive 96/54/EC Method B1 Tris acute toxicity
Mortality:	No deaths were reported.
Clinical observations:	Pink staining of the fur was noted in all animals one to four days after dosing. No other signs of systemic toxicity were reported. All animals showed expected gains in bodyweight over the study.
Morphological findings:	No abnormalities were noted at necropsy.
LD_{50}:	> 2000 mg/kg body weight
Result:	the notified chemical plus additive was of very low acute oral toxicity in rats.

9.1.2 Dermal Irritation, ST383 (Safepharm Laboratories, 2000b).

Species/strain:	rabbit: New Zealand White

Number/sex of animals:	3 male
Observation period:	72 hours
Method of administration:	A single 4-hour, semi-occluded application of 0.25 g in 1.0 mL notified chemical to the shorn intact skin.
Test method:	OECD TG 404; Directive 92/69/EEC Method B4 Acute Toxicity (Skin Irritation)
Dermal observations:	No signs of irritation or corrosive effects were observed. Pink staining was observed at all treated skin sites during the study.
Morphological findings:	None reported.
Comment:	The notified chemical produced a primary irritation index of 0.0, hence was classified as a non-irritant according to the Draize classification scheme.
Result:	the notified chemical plus additive was not a skin irritant in rabbits

9.1.3 Eye Irritation, ST383 (Safepharm Laboratories, 2000c).

Species/strain:	New Zealand White rabbit
Number/sex of animals:	3 male
Observation period:	72 hours
Method of administration:	Single application of 0.1 mL (20 mg) to the right eye; the left eye served as control; eyes were not irrigated.
Test method:	OECD TG 405; Directive 92/69/EEC Method B5 Acute toxicity (Eye Irritation)

Draize scores of unirrigated eyes:

	Time after instillation								
Animal	***1 day***			***2 days***			***3 days***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	1sf	0	0	0sf	0	0	0sf
2	0	0	0sf	0	0	0sf	0	0	0sf
3	0	0	0sf	0	0	0sf	0	0	0sf

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge sf= pink staining of fur around the eye

Comment: Pink staining of the fur around the treated eye was noted in all three animals throughout the study. Minimal conjunctival irritation in all animals at 1 hour and in one at 24 hours post treatment. No corneal or iridial effects were noted during the study. The notified chemical (plus additive) produced a maximum group mean score of 3.3 and was classified as a practically non-irritant to the rabbit eye according to a modified Kay and Calandra classification system.

Result: the notified chemical plus additive was slightly irritating to the eyes of rabbits.

9.1.4 Skin Sensitisation, ST463 (Huntington Life Sciences, 2001a)

Species/strain: Guinea pig/ Hartley White

Number of animals: 15 female (10 test, 5 control animals)

Method of administration: Intradermal injection: 2.5 % w/v
Topical application: 50 % w/v
Challenge application: 50 and 25 % w/v
The vehicle used in all cases was Alembicol D (derivative of coconut oil)

Positive control: hexyl cinnamic aldehyde

Induction procedure:

Test group

day 1 Pairs of intradermal injections (0.1 mL) to the scapular region as follows:

- Freund's Complete Adjuvant (FCA), 1:1 in water;
- ST463, 2.5% w/v in Alembicol D;
- ST463, 2.5% w/v in FCA, 1:1 in Alembicol D.

day 6 10% w/v sodium lauryl sulphate

day 7 50% w/v ST463 in Alembicol D under occlusive patch for 48 hours

Control group

Treated similarly to the test animals except that the test substance was omitted from the intradermal injections and the topical application.

Challenge procedure:

day 22

Topical application on the flank of ST463, 50 and 25% w/v in Alembicol D for 24 hours under occlusive dressing. Control animals treated similarly except that the test substance was omitted from the topical application.

Test method: OECD TG 406; EPA Health Effects Test Guidelines, EPA 712-C-98-197.

Comments: ST463 did not produce a positive skin reaction of skin sensitisation in any of the test animals. No animals showed abnormal clinical signs or body weight change.

9.1.5 Local Lymph Node Assay in the Mouse, ST383 (Huntington Life Sciences Ltd, 2000)

Species/strain: CBA/Ca mice

Number of animals: 16 female

Vehicle: Acetone/olive oil 4:1 v/v acetone/olive oil (AOO)

Dosing schedule: 5, 10 and 20 % w/v in AOO.

Method of administration: Three groups of four mice were treated by daily application of 25 microlitres of each dosage and control to the dorsal surface of both ears for three consecutive days. Positive controls used were hexyl cinnamic aldehyde (HCA) and 2-mercaptobenzothiazole (MBT). ^{3}H-methyl thymidine was used as a radiolabel.

Test method: (Kimber *et al.*, 1989; Basketter & Scholes, 1992)

Mortality: No mortality was reported.

Clinical observations: No signs of ill health or toxicity were observed. Red staining behind the ears was noted for all groups receiving the notified chemical. No significant body weight increases were recorded.

Comment: Proliferative response of the lymph node is expressed as the group mean disintegrations per minute (DPM)/lymph node for the vehicle control and each test concentration. The stimulation index is obtained by calculating the ratio of the test substance DPM/lymph node to that of the vehicle control (test/control ratio). The test/control ratios reported for 5, 10 and 20 % w/v are 1.9, 1.2 and 1.1 respectively,

indicating that ST383 did not show the potential to induce skin sensitisation. A positive response includes a stimulation index of ≥ 3.0 at one or more test concentrations, together with consideration of a dose-response. The positive controls showed a stimulation index of ≥ 3, validating the assay.

Result: On the basis of the lymphocyte proliferative response the notified chemical plus additive is not considered to be a sensitiser under the conditions stated.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay, ST383 (Canon Inc, 2001a).

Strains: TA98 and TA100

Test Substances: ST383

Metabolic activation: Rat liver S9 fraction from animals pretreated with phenobarbital and 5,6-benzoflavone. 2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide and 2-aminoanthracene in DMSO were used as positive controls. DMSO was the solvent control.

Concentration range: In Exp 1 the range was 19.53, 78.13, 312.5, 1250 and 5000 microgram/plate, +/- S9 with TA98 and TA100. In Exp 2 the range was 0.02, 0.08, 0.31, 1.22, 4.88, 19.53, 78.13 and 312.5 microgram/plate without S9 with TA100. In Exp 3, the range was 0.61, 1.22, 2.44, 4.88, 9.77, 19.53, 39.06, 78.13, 156.25 and 312.5 microgram/plate (-S9) with TA100; 312.5, 625, 1250, 2500 and 5000 microgram/plate (-S9) with TA98; 625, 1250, 2500, 5000 and 10000 microgram/plate (+S9) with TA100; 312.5, 625, 1250, 2500, 5000 and 10000 microgram/plate (+S9) with TA98.

Test method: "According to Standards for Mutagenicity Test Using Microorganisms of the Japanese Occupational Safety and Health Law".

Comment: In all experiments, less than a doubling of revertant colony numbers was observed, hence the notified chemical was deemed non-mutagenic. Both positive and negative controls yielded appropriate revertant colony numbers. Cytotoxicity was observed for TA 100 in the absence of S9 at higher doses.

Result: The notified chemical was non mutagenic under the conditions of the test.

9.2.2 *Salmonella typhimurium* Reverse Mutation Assay, ST463 (Canon Inc, 2001b).

Strains:	TA98 and TA100
Metabolic activation:	Rat liver S9 fraction from animals pretreated with phenobarbital and 5,6-benzoflavone. 2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide and 2-aminoanthracene in DMSO were used as positive controls. DMSO was the solvent control.
Concentration range:	Concentrations of 0.001, 0.003, 0.01, 0.06, 0.32, 1.6, 8, 40, 200, 1000 and 5000 microgram/plate, (-S9) in were used in Exp 1. Concentrations of 1.6, 8, 40, 200, 1000 and 5000 microgram/plate (+ S9) were used. In Exp 2, concentrations of 4.9, 9.8, 19.5, 39, 78, 156.3, 312.5, 625, 1250 and 2500 microgram/plate (-S9) were used. In Exp 2, concentrations of 39, 78, 156.3, 312.5, 625, 1250, 2500 and 5000 microgram/plate (+ S9) were used. In Exp 3, the range extended 9.8, 19.5, 39, 78, 156.3, 312.5, 625, 1250, 2500 and 5000 microgram/plate (-S9) and 312, 625, 1250, 2500, 5000 and 10000 microgram/plate (+S9).
Test method:	"According to Standards for Mutagenicity Test Using Microorganisms of the Japanese Occupational Safety and Health Law".
Comment:	In all experiments, less than a doubling of revertant colony numbers was observed, hence the notified chemical was deemed non-mutagenic. Both positive and negative controls yielded appropriate revertant colony numbers. Cytotoxicty was observed in both strains (predominantly in TA 100) in (-S9) at higher doses.
Result:	The notified chemical was non mutagenic under the conditions of these tests.

9.2.2 Chromosomal Aberration Assay in Human Lymphocytes, ST463 (Huntington Life Sciences Ltd, 2001b)

Cells:	Human lymphocytes; human blood from healthy non-smoking males.
Metabolic activation system:	Rat liver S9 fraction from male Sprague-Dawley rats pretreated with Aroclor 1254
Dosing schedule:	See below:

• *Metabolic Activation*	• ***Experiment Number***	• *Test concentration (microgram/mL)*	• *Controls*
-S9	1	treatment time = 3 hours 0* (culture medium) 312.5* 625* 1250*	Positive: Mitomycin C (0.1 microgram/mL) Negative: culture medium
+S9		0* 312.5* 625* 1250*	 Positive: CP (6 microgram /mL) Negative: culture medium
-S9	2	treatment time = 20 hours 0* (culture medium) 156.2* 312.5* 625*	Positive: Mitomycin C (0.1 microgram/mL) Negative: culture medium
+S9		treatment time = 3 hours 0* 312.5* 625* 1250*	 Positive: CP (6 microgram /mL) Negative: culture medium

CP - cyclophosphamide
* - cultures selected for metaphase analysis

Test method: OECD TG 473; US EPA Guideline 712-C-98-223.

Comment: Exp 1: Comprehensive experimental tests were conducted, and at an apparent high level of quality. In both the absence and presence of S9, ST463 caused no significant reduction in the mitotic index at the six first dose levels (from 39 to 1250 microgram/mL) as *cf*. solvent control. Due to the high levels of red precipitates observed in treated cultures at 2500 and 5000 microgram/mL, mitotic indices could not be scored. As such, 312.5, 625 and 1250 microgram/mL were chosen for metaphase analysis. The quantitative analysis for polyploidy of these doses showed no increases in the number of polyploid metaphase figures *cf*. solvent control.

In the metaphase analysis, there was no statistically significant increase in the proportion of cells with chromosomal aberrations, at any dose level, with or without S9 *cf*. solvent control. Both positive controls performed within historical values.

Exp 2: In the absence of S9, ST463 caused no significant reduction in the mitotic index at 39 to 625 microgram/mL as *cf*. solvent control. Due to the high levels of red precipitates observed in treated cultures at 1250 microgram/mL, mitotic indices could not be scored. As such, 156.3, 312.5 and 625 microgram/mL were chosen for metaphase analysis. The quantitative analysis for polyploidy of these doses showed no increases in the number of polyploid metaphase figures *cf*. solvent control. In the presence of S9, ST463 caused no significant reduction in the mitotic index at any level *cf*. solvent control. Therefore, 312.5, 625 and 1250 microgram/mL were chosen for metaphase analysis. The quantitative analysis for polyploidy of these doses showed no increases in the number of polyploid metaphase figures *cf*. solvent control.

In the metaphase analysis, there was no statistically significant increase in the proportion of cells with chromosomal aberrations, at any dose level, with or without S9 *cf*. solvent control. Both positive controls performed within historical values.

Result: The notified chemical was non clastogenic under the conditions of the test.

9.3 Overall Assessment of Toxicological Data

Toxicological data were collected on the notified chemical, NT-20, and a mixture of notified chemical plus 10% additive, ST383. ST383 was found to have very low acute oral toxicity in rats, was not a skin irritant in rabbits, was slightly irritating to the eyes of rabbits and not a sensitiser in the mouse local lymph node assay. NT-20 was a non-sensitiser in guinea pigs. In the genetic toxicology assays, ST383 and NT-20 were non mutagenic in two separate assays using *Salmonella typhimurium* strains TA 98 and TA 100. ST383 was non clastogenic in the Chromosomal Aberration Assay using human lymphocytes.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical entering the environment will be fused to paper during the photocopying process. Waste paper will be disposed of through landfill, recycling, or incineration. In landfill, the toner (and the notified chemical) should remain fixed to the paper substrate and remain immobile. When the paper is recycled, waste sludge containing the notified chemical will be disposed to landfill. Due to the negligible solubility of the notified chemical, most will remain bound to the sludge in landfill and will not be available to the environment. Incinerated paper/toner wastes will generate carbon oxides and water and do not present a significant environmental hazard.

Accidental spillage of the chemical, either during replacement of cartridges and bottles or during transport, should result in powder wastes being sent to either landfill or incineration facilities. Spent cartridges and bottles that are not recycled are likely to be sent to landfill. As a worst case, a maximum of 200 kg/year of the notified chemical could be sent to landfill in containers. The disposal of cartridges and bottles would be widespread across Australia.

Significant leaching of the notified chemical from landfill is not expected given that the chemical is practically insoluble. The overall environmental risk presented by the importation of the notified chemical is low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Based on the toxicological data provided, the notified chemical would not be acutely toxic via the oral route. It is not likely to be a skin sensitiser or to be genotoxic. It is not likely to be a skin irritant but could be a slight eye irritant. The notified chemical would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data provided. The MSDS for the toner to be imported states that the toner would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety

Exposure to toner containing the notified chemical during transport of pre-filled cartridges or bottles should not result in exposure except in the event of accidental spillage.

The notified chemical will be in imported toner cartridges and bottles at a maximum of 5%. Dermal exposure of office workers to the notified chemical will potentially occur when replacing spent cartridges and bottles and clearing paper jams from the printer or photocopier. However, the design of the cartridges and bottles is such that exposure to the notified chemical and risk of adverse health effects should be negligible.

Dermal exposure of maintenance workers to the notified chemical is possible during routine maintenance but is expected to be low due to the low concentration of the notified chemical in the toner. However, due to their frequent exposure to toners, maintenance and printer/photocopier personnel should wear cotton or disposable gloves.

It has been estimated that the atmospheric level of toner during machine operation is less than 1 milligram per cubic metre. A level greater than this would not be expected for workers changing containers or involved in machine maintenance. Therefore, the risk of adverse health effects from atmospheric levels of the notified chemical would be negligible.

While ocular exposure to toner dust may occur the risk of eye irritation in workers involved in transport, storage, use and disposal of the notified chemical in this application is low.

In the event that the notified chemical will be handled as a raw ingredient at high concentrations, workers should be protected from skin contamination because it has staining properties.

Public Health

The potential for public exposure during the transport of new cartridges and bottles to distribution outlets is negligible. Exposure may result from the use of the product at work sites or at the home office. Any such exposure is likely to be minimal and limited to the skin of the hands or the eye. The outcome of such exposure is likely to be of little consequence since NT-20 does not appear to be a skin irritant or a skin sensitiser and is a mild eye irritant. At the concentration of the notified chemical in toner, it is not expected to pose a significant health risk.

13. RECOMMENDATIONS

To minimise occupational exposure to NT-20, the following guidelines and precautions should be observed:

- Protective eyewear, clothing and gloves should be worn when handling the notified chemical;
- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

No special precautions are required for the notified chemical when used at low quantities in printer or photocopier cartridges or bottles. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Service personnel should wear cotton or disposable gloves when removing spent cartridges or bottles containing the notified chemical or when servicing printers or photocopiers.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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.

15. REQUIREMENTS FOR 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(1) of the Act; if
- toner products containing the notified chemical at a level greater than 5% are to be introduced.

or

(2) 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.

16. REFERENCES

Australian Environmental Review 16 (1), January 2001, pp. 16

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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