File No: PLC/321

3 October 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NT-17

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

National Occupational Health and Safety Commission 25 Constitution Avenue CANBERRA ACT 2600 AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX + 61 2 8577 8888. Website: www.nicnas.gov.au

Director Chemicals Notification and Assessment

TABLE OF CONTENTS

ULL PUBLIC REPORT	
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	
3. COMPOSITION	
4. INTRODUCTION AND USE INFORMATION	
5. PROCESS AND RELEASE INFORMATION	
5.1. Distribution, Transport and Storage	
5.2. Operation Description	
5.3. Occupational exposure	
5.4. Release	
5.5. Disposal	
5.6. Public exposure	6
6. PHYSICAL AND CHEMICAL PROPERTIES	
7. TOXICOLOGICAL INVESTIGATIONS	
8. ENVIRONMENT	
9. RISK ASSESSMENT	
9.1. Environment	
9.1.1. Environment – exposure assessment	
9.1.2. Environment – hazard assessment	
9.1.3. Environment – risk characterisation	
9.2. Human health	
Occupational health and safety – exposure assessment	
Public health – exposure assessment	
Human health - effects assessment	
Occupational health and safety – risk characterisation.	
Public health – risk characterisation	
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONME	
HUMANS	
10.1. Hazard classification	
10.2. Environmental risk assessment	
10.3. Human health risk assessment	
10.3.1. Occupational health and safety	
10.3.2. Public health	
11. MATERIAL SAFETY DATA SHEET	
11.1. Material Safety Data Sheet	
11.2. Label	
12. RECOMMENDATIONS	
12.1. Secondary notification	
13. BIBLIOGRAPHY	10

FULL PUBLIC REPORT

NT-17

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

The notified polymer meets the PLC criteria.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name; Other name; CAS number; Molecular and structural formulae; Means of identification; Molecular weight, Charge Density, Polymer constituents; Residual monomers and impurities; Reactive functional group; Exact import volume; Site of manufacture/reformulation; Purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES US-EPA (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) NT-17

3. COMPOSITION

DEGREE OF PURITY High

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer will be imported in sealed cartridges or bottles as a component of photocopier and printer toners. The notifier does not intend to manufacture the new polymer in Australia in the foreseeable future.

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

Year	1	2	3	4	5
Tonnes	Up to 100				

USE

The notified polymer will be used as a component of a toner for electrophotocopying machines and electrophotographic printers. The notified polymer transfers the toner during the copier and printer operations.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

TRANSPORTATION AND PACKAGING

The notified polymer will be imported, distributed and supplied to consumers in 0.2-4 L sealed cartridges or bottles containing between 100-2500 g of toner. The toner contains 85-97% notified polymer.

5.2. Operation Description

The notified polymer will be imported as a component of a toner in sealed containers. The containers are designed such that release of toner is not expected unless the shutter is opened or the seal tape is removed. Replenishment of the toner is required when its performance is lost during copying and printing. This is done by removing the seal tape from the container and fitting it into the photocopier or printer. The toner can also be replenished by attaching a specifically designed container into the photocopier. For larger machines, it is likely that trained service personnel will carry out toner replenishment.

5.3. Occupational exposure

Office workers, and printer and photocopier maintenance workers may be intermittently exposed to the notified polymer when replacing the spent toner, and during maintenance and cleaning of printers or photocopiers. Maintenance workers may potentially come in contact with the notified polymer more often than office workers. Exposure would be principally by skin contamination, however, inhalation exposure is possible, particularly if spillage occurs. The toner containing the notified polymer contains an average particle size of 5-10µm (respirable particles). However, exposure is expected to be controlled through the design of the toner container and the photocopiers and printers. Printer and photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed toners are sealed and worker exposure to the toner is 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 polymer unless the packaging is breached.

5.4. Release

RELEASE OF CHEMICAL FROM USE

Release of the toner containing the notified polymer to the environment is not expected under normal use as each toner container is designed to prevent leakage.

Environmental release may result from the disposal of toner-impregnated printer paper and discarded bottles/cartridges that are not recycled as well as the possibility of accidental leakage from the bottles/cartridges during use.

5.5. Disposal

Some waste paper may be disposed of directly to landfill with the notified polymer strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer. Incineration of waste paper will destroy the compound and will generate water vapour and oxides of carbon.

In addition to landfill, some of the printed-paper will enter the paper recycling process. During such processes, waste paper repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner/toner detachment from the fibres, pulp brightness and the whiteness of paper. These wastes are expected to go to trade waste sewers. Trade sources estimate the washing process will recover 30-60% of the total amount of the toner and therefore at least 30% of the notified polymer in the recycled paper will be disposed of with sludge in landfill.

The notifier estimates that approximately 1 to 5 % (1 to 125 grams) of the notified polymer may remain in the used bottle/cartridge.

The total import volume of the notified polymer will ultimately be disposed of by either landfill or incineration.

5.6. Public exposure

Public exposure may result from dermal contact with the toner deposited onto printed papers. Exposure to the public may also occur during an accidental spillage. If this should occur, the spilled powder should be swept slowly on to paper, and be carefully transferred into a sealable waste container. The remainder should be wiped up with wet paper, cloth or mop. Inhalation of the dust should be avoided, and a vacuum cleaner is not recommended to clean up spilled powder. In case of large spill, eliminate all sources of ignition including sparks and static electricity. Disposal should be subject to federal, state or local laws.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White powder

Melting Point/Freezing Point $85.5 - 91.5 \pm 0.5$ °C

METHOD EC Directive 92/69/EEC A.1 Melting/freezing temperature and OECD TG 102

Melting Point/Melting Range

TEST FACILITY Safepharm Laboratories Limited (2001a)

Density $1.2 \times 1000 \text{ kg/m}^3 \text{ at } 19.0 \pm 0.5 \text{ °C}$

METHOD EC Directive 92/69/EEC A.3 Relative density and OECD TG 109 Density of

Liquids and Solids

TEST FACILITY Safepharm Laboratories Limited (2001a)

Water Solubility $< 1.2 \times 10^{-3} \text{ g/L of solution at } 20.0 \pm 0.5 \,^{\circ}\text{C}$

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

solubility

TEST FACILITY Safepharm Laboratories Limited (2001a)

Particle Size $<100 \mu m = 13.3\%$ $<10 \mu m = 11.8\%$

Remarks The result indicates that 11.8% by mass of particles which, if inhaled can be

expected to achieve alveolar deposition in humans.

METHOD EC Directive Guidance 'Particle Size Distribution, Fibre Length and Diameter

Distribution'

TEST FACILITY Safepharm Laboratories Limited (2001a)

Flammability Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (solids)

TEST FACILITY Safepharm Laboratories Limited (2001b)

Explosive Properties

Not determined

Remarks The notified polymer is not expected to have explosive properties based on the

chemical structure.

Degradation Products

none

Loss of monomers, other reactants, additives impurities

none

ADDITIONAL TESTS

Vapour Pressure

<1.7 X 10⁻⁷ kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour pressure

OECD TG 104 Vapour pressure

TEST FACILITY Safepharm Laboratories Limited (2001c)

Hydrolysis as a Function of pH

Not determined

Remarks The notified polymer contains linkages that are unlikely to undergo significant

hydrolysis in the environmental pH range of 4 to 9 due to its low solubility in

water

Partition Coefficient (n-octanol/water)

 $>1.59x10^6$ or

 $\log Pow$ at $20^{\circ}C = greater$ than 6.2

Remarks Given the notified polymer's expected low water solubility and likely

hydrophilic nature it would partition into the aqueous phase, except if present in

its acid form where it would be more lipophilic.

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient and OECD TG 117 Partition

Coefficient (n-octanol/water) HPLC Method.

TEST FACILITY Safepharm Laboratories Limited (2001a)

Adsorption/Desorption

 $log K_{oc} = greater than 3.41$

Remarks Estimated using Quantitative Structure Activity Relationships (QSAR). In its acid

form the notified polymer is expected to adsorb to, or be associated with, soil/sediment and organic matter and be immobile in soil due to its low water

solubility.

Dissociation Constant

pKa = Approximately 3 to 4.5

Remarks Carboxylic acid is known to have pKa's between 4-5. The notified polymer is

essentially insoluble in water.

Oxidising Properties

Not determined

Remarks The oxidising test was not conducted, however, the notified polymer is expected to

be non-oxidising based on its chemical structure.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological studies for the following endpoints were submitted for the notified polymer. The results are either negative or did not meet the criteria for classification as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Endpoint and Result

Assessment Conclusion

Rat, acute oral LD50 >2500 mg/kg bw	very low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Genotoxicity - bacterial reverse mutation	non mutagenic

8. ENVIRONMENT

No ecotoxicological data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure resulting from disposal of toner-impregnated printer paper, discarded bottles and cartridges that are not recycled, and accidental leakage of the bottles and cartridges during use will be collected and sent to landfill for disposal. Spent bottles or cartridges will be collected by a recovery system for recycling and re-use. Residues contained in the empty bottles and cartridges are expected to remain within these containers, although release could also occur from deterioration of these containers.

9.1.2. Environment – hazard assessment

No ecotoxicological data were submitted for the notified polymer. Under normal usage, there will be limited release to the aquatic compartment. The notified polymer is not expected to bioaccummulate due to its low water solubility and high molecular weight (Connell, 1990).

9.1.3. Environment – risk characterisation

The notified polymer will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded cartridges at landfill sites. Based on the import volume, method of packaging and low concentration of the notified polymer in printer toner, release of the notified polymer to the environment is expected to be low but widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer.

Abiotic or slow biotic processes would be largely responsible for the degradation of the notified polymer. As a consequence of its low water solubility, the notified polymer is likely to be immobilised through adsorption onto soil particles and sediments.

Bioaccumulation of the notified polymer is not expected due to its low water solubility and large molecular weight, which will inhibit passage through cell membranes.

On the basis of the available information, the overall environmental risk of the notified polymer is expected to be low.

9.2. Human health

Occupational health and safety – exposure assessment

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

Dermal and inhalation exposure of office workers to the notified chemical will potentially occur when replacing spent cartridges and clearing paper jams from the printer or photocopier.

Dermal and inhalation exposure of maintenance workers to the notified chemical is possible during routine maintenance. Due to the probable fine nature of the toner, skin, eye and

FULL PUBLIC REPORT PLC/321 respiratory exposure should be avoided. The NOHSC exposure standard for nuisance dusts is 10 mg/m³ time weighted average (TWA) (NOHSC, 1995). Australia has no exposure standard for respirable dust, however, the ACGIH TLV of 3 mg/m³ TWA is recommended (ACGIH, 2001). Due to their frequent exposure to toners, maintenance personnel should wear cotton or disposable gloves. However, the design of the cartridges is such that exposure to the notified polymer should be low. The predicted airborne concentration of toner dust in the vicinity of a photocopier is <0.1 mg/m³ (EASE, 1997).

Public health – exposure assessment

There is low potential for public exposure to the notified polymer during transportation, handling and usage of the toner unless accidental spillage occurs. Public exposure with trace amounts of toner which may be lifted off from the printed-paper is also expected to be low. The pattern of package and usage of the toner containing the notified polymer is unlikely to pose a significant exposure to public health.

Human health - effects assessment

The notified polymer has very low acute oral toxicity. It is non-irritating to the skin but slightly irritating to the eyes. It gave a negative result in a bacterial mutagenicity test.

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

The powder may cause mechanical irritation to the eyes, and to the respiratory tract if inhaled.

Occupational health and safety - risk characterisation

The OHS risk presented by the notified polymer is expected to be low due to the limited contact to the toner when in use, the presence of adequate ventilation in the workplace and the use of disposable gloves by maintenance personnel.

Photocopiers and printers should be positioned in well-ventilated areas. Employers are responsible for maintaining nuisance dust level below the NOHSC exposure standard.

The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public health - risk characterisation

Members of the public may make dermal contact to printed papers from photocopy and printing equipment. Following printing application, the notified will become trapped within a film and will not be bioavailable. Therefore, the risk to the public from exposure to the notified polymer is considered negligible.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10.2. Environmental risk assessment

The polymer 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 the notified polymer is used as a component of toners.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

The label for the product containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Service personnel should wear cotton or disposable gloves when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.
- Photocopiers and printers should be positioned in well-ventilated areas. Employers should ensure that inhalation exposure to dust is maintained below the NOHSC exposure standard for nuisance dust.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

• The notified polymer should be disposed of by landfill.

Emergency procedures

• Spills/release of the notified polymer should be contained as described in the MSDS. Sweep spilt material onto paper and transfer to a sealable waste container. Disposal should be subject to Federal, State and Territory or local laws.

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(1) of the Act; if

 the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

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.

13. BIBLIOGRAPHY

ACGIH, (2001); The American Conference of Governmental Industrial Hygienists (ACGIH): Threshold Limit Values for Chemical Substances and Physical Agents and Biological Indices 2001; ACGIH Cincinnati, Ohio.

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

Ease for Windows Version 2.0, August (1997). A system for the Estimation and Assessment of Substance Exposure (EASE). The Health and Safety Executive, U.K.

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

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

National Occupational Health and Safety Commission (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]. In: Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Safepharm Laboratories Limited (2001a). ST592MO: Determination of General Physico-chemical Properties (Project No: 1091/028). Derby, UK, Safepharm Laboratories Limited (unpublished report submitted by Canon Australia Pty Ltd).

Safepharm Laboratories Limited (2001b). ST592MO: Determination of Hazardous Physico-chemical Properties (Project No: 1091/029). Derby, UK, Safepharm Laboratories Limited (unpublished report submitted by Canon Australia Pty Ltd).

Safepharm Laboratories Limited (2001c). ST592MO: Determination of Vapour Pressure (Project No: 1091/030). Derby, UK, Safepharm Laboratories Limited (unpublished report submitted by Canon Australia Pty Ltd).