File No LTD/1146

26 July 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NT-9

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:

Library
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
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

NT-9

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd
1 Thomas Holt Drive
North Ryde, Sydney N.S.W 2113

NOTIFICATION CATEGORY
Limited-small volume: Polymer with NAMW < 1000 (1 tonne or less per year).

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

Identity of chemical
Composition
Actual volume of manufacture or import

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a function of pH
Partition coefficient
Dissociation constant
Flash point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US-EPA (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NT-9

3. COMPOSITION

DEGREE OF PURITY
100%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a photocopier developer in sealed cartridges or bottles. The notifier does not intend to manufacture the new chemical in Australia in the foreseeable future.

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

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

USE
The notified polymer will be used as a component of a developer for electrophotocopying machines and electrophotographic printers. The coated carrier containing the notified polymer (30-100 μm particle size) 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.

IDENTITY OF MANUFACTURER/RECIPIENTS
Canon Australia Pty Ltd
1 Thomas Holt Drive
North Ryde NSW 2113

TRANSPORTATION AND PACKAGING
The notified polymer will be imported, distributed and supplied in 0.25 to 1.25 L sealed cartridges or bottles containing between 200-500 g of developer to consumers. The developer contains <1% notified polymer.

5.2. Operation Description

The notified polymer will be imported as a component of a developer for electrophotocopying machines or electrophotographic printers in sealed bottles or cartridges. The developer bottle or cartridge is designed so that release of developer is not expected unless the shutter is opened or the seal tape is removed. Exchange of the developer is required when its performance is lost during use. The developer is replaced by attaching a specifically designed plastic bag into the copying machine or printer. The used developer is transferred to the bag, the bottle or cartridge refilled with new developer, and the bag is then sealed and removed. For larger machines, it is likely that trained service personnel will carry out developer replenishment.

5.3. Occupational exposure

Office workers and printer maintenance workers may be intermittently exposed to the notified polymer when replacing the spent cartridge or bottle, 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 could also occur, particularly if spillage occurs. The coating carrier containing the notified polymer contains non-respirable particles (30-100 μm). In addition, exposure is expected to be controlled through the design of the developer cartridge or bottles and the printing and photocopier machines. Printer and photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed developer cartridges are sealed and worker exposure to the developer 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

The developer containing the notified polymer will be imported in sealed cartridges or bottles and there will be no release to the environment due to reformulation or repackaging. Release of the developer containing the notified polymer to the environment is not expected during copying or printing operations. The notifier claims that no spillage is expected during the exchange of developer containing the notified polymer (as described in Section 5.2) although small amounts may be lost due to accidental spills. The notified polymer is used to assist the transfer of toner during the copying or

printing but doesn't transfer itself out of the copying machine or printer. It is recycled within the cartridge or bottle and is not expected to transfer on to the paper or be released into the environment during use.

The total amount of the notified polymer imported (up to 1 tonne per annum) is expected to be disposed of when the developer containing it is removed from the machines. The sealed cartridges or bottles are contained within the photocopier until they are eventually removed for disposal.

5.5. Disposal

The waste developer should be disposed of in accordance with the federal, state and local regulations. The specific details of the method of disposal of the developer containing the notified polymer and the cartridges/bottles are not provided. It is expected that the waste developer removed and the containers will be disposed of in landfill.

5.6. Public exposure

There is potential for public exposure in the event of 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.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa

Melting Point Not determined

METHOD	OECD TG 102 Melting Point.
Remarks	The notified polymer decomposes at temperatures above 220 ºC without melting.
TEST FACILITY	Huntingdon Life Sciences Ltd (2003a)

Boiling Point Not determined

METHOD	OECD TG 103 Boiling Point.
Remarks	The notified polymer decomposes at temperatures above 220 ºC without melting.
TEST FACILITY	Huntingdon Life Sciences Ltd (2003a)

Relative Density 1.18 at 23ºC

METHOD	OECD TG 109 Density of Liquids and Solids.
TEST FACILITY	Huntingdon Life Sciences Ltd (2003a)

Vapour Pressure 2.4×10^{-11} kPa at 25ºC

METHOD	OECD TG 104 Vapour Pressure.
Remarks	A vapour pressure balance between 139°C and 180°C and linear regression analysis was used to calculate vapour pressure at 25°C. According to the results, the test substance is very slightly volatile (Mensink e*t al*. 1995).
TEST FACILITY	Huntingdon Life Sciences Ltd (2003a)

Water Extractivity 3.48 (0.35%) to 24.8 (0.25%) mg C/L at 20°C

METHOD	OECD TG 120 Water Extractivity.
Remarks	A preliminary assessment indicated a water solubility of less than 1 mg/L.
	In a subsequent extractivity test six samples (three each of 10 g and 1 g sieved to <250 μm) of the test substance and a blank sample were shaken with 1000 mL of purified water at 20 ± 1°C for 24 hours. The samples were filtered (0.45 μm, nitrocellulose, vacuum filtration) and each filtrate was measured for total organic

carbon content (TOC) and the residues were measured gravimetrically.

The mean TOC was found to be between 3 and 25 mg C/L depending on loading. The higher carbon content (24.8 mg C/L) was observed at higher dose levels, however, this represents a lower extractivity (0.25%). Based on the increased extractivity with test concentration and the preliminary water solubility results the report suggested that the impurities rather than the test substance itself were the soluble components.

TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Hydrolysis as a Function of pH Not determined.

Remarks Hydrolysis as a function of pH of the notified polymer could not be determined due to its low water solubility and the lack of sufficiently sensitive specific method of analysis. The polymer does contain functionalities which are generally considered to be hydrolysable but this should not occur at ambient conditions in the environmental pH range of 4 to 9.

TEST FACILITY Huntingdon Life Sciences Ltd (2003b)

Partition Coefficient (n-octanol/water) Not determined.

Remarks A partition coefficient was not determined for this notification due to the notified polymer's low water solubility and insolubility in the solvents used in the HPLC method.

The low water solubility and the estimated high adsorption coefficient of the test substance may indicate a high affinity for the organic phase.

TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Adsorption/Desorption Estimated log K_{oc} = >3.6

Remarks The K_{oc} was estimated using the following empirical relationship:

$$\log_{10} K_{oc} = -0.55 \log_{10} S + 3.64$$

Where S is the water solubility (<1 mg/L based on the preliminary test results).

According to the results, the test substance slightly mobile (Mensink e*t al*. 1995) and will adsorb to or associate with soils/sediments.

TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Dissociation Constant Not determined.

Remarks Dissociation constant was not determined due to the notified polymer's low water solubility. The polymer contains a primary amine, which is expected to display typical basicity.

Particle Size 6% by mass smaller than 10 μm
30-100 μm (coated carrier containing the notified polymer)

METHOD OECD TG 110 Particle Size Distribution

Range (μm)	*Mass (%)*
>400	0.2
400 – 125	8.1
125-75	16.5
75-30	48.0
30-10	27.1
<10	0

TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified polymer charred but failed to ignite.
TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Autoignition Temperature 292ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

Oxidizing Properties Non-oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Huntingdon Life Sciences Ltd (2003a)

7. TOXICOLOGICAL INVESTIGATIONS

Acute oral toxicity and bacterial reverse mutation studies were submitted for the notified polymer. No other toxicity data for the notified polymer were submitted.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2500 mg/kg bw	low toxicity
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer.

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley CD (Crl: CD (SD) IGS BR).
Vehicle Arachis Oil BP
Remarks – Method The test material was prepared as a suspension in arachis oil BP at the appropriate concentration. All animals were dosed once only by gavage. The animals were observed for deaths or signs of toxicity at ½, 1, 2 and 4 hours after dosing and subsequently once daily for fourteen days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 (female)	2000	0/3
II	3 (female)	2000	0/3

LD50 >2500 mg/kg bw.
Signs of Toxicity There were no signs of systemic toxicity.
Effects in Organs No abnormalities were noted at necropsy.
Remarks – Results None.

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	SafePharm Laboratories (2003).

7.2 Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	Japanese Occupational Safety and Health Law - Standards for Mutagenicity Test using Microorganisms
Species/Strain	*S. typhimurium*: TA98 and TA100, TA 1535, TA 1537 *E. coli*: WP2 uvrA (pKM101) (CM891)
Metabolic Activation System	10 % rat liver S9 fraction from animals pretreated with Aroclor 1254
Concentration Range in Main Test	a) Test 1, with and without metabolic activation: 5, 15, 50, 150, 500, 1500, and 5000 µg/plate. b) Test 2, with and without metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate
Vehicle	Suspension in water .
Remarks - Method	Two separate tests were performed in triplicate.
RESULTS	
Remarks - Results	No substantial increases in the number of revertant colonies were seen in any strain either in the presence or absence of metabolic activation.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences Ltd. (2003c)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate including bioaccumulation data was submitted. The low water solubility may indicate a potential for bioaccumulation. However, considering the high molecular weight and very low (if any) release to the aquatic compartment, this potential is not expected to be high.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is expected to remain in the cartridge or bottle during photocopying or printing and is not expected to transfer on to the paper or be released into the environment. Therefore, the entire amount of the polymer imported (up to 1 tonne per annum) is expected to be disposed of to landfill, either with the developer removed from the machines or as residue in sealed cartridges or bottles removed for disposal.

The partition coefficient was not determined for the notified polymer, however, based on the low water solubility and high estimated adsorption coefficient the polymer is unlikely to be mobile in a landfill and would become associated with the organic component of soils and

sediments. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer.

No environmental fate data including bioaccumulation data were submitted. The low water solubility and the high estimated adsorption coefficient of the notified chemical may indicate a potential for bioaccumulation. However, considering the high molecular weight of the notified polymer and very low (if any) release to the aquatic compartment, this potential is not expected to be high.

The very limited exposure to the aquatic compartment makes it very difficult to calculate a meaningful predicted environmental concentration (PEC).

9.1.2. Environment – effects assessment

No ecotoxicological data were available to assess the environmental effects of the notified polymer. The notified polymer has the potential to be cationic with a functional group equivalent weight (FGEW) of less than 5000. Cationic polymers are known to be six times more toxic to algae than to fish (Nabholz et al. 1993).

9.1.3. Environment – risk characterisation

It is not possible to determine a realistic PEC value in order to assess the risk to aquatic organisms, as the use pattern of the notified polymer will result in very low exposure to the aquatic environment. The notified polymer has the potential to be toxic to aquatic organisms, although it is unlikely to exist at levels which could accumulate and pose a risk to aquatic organisms due to the diffuse nature of use and limited release to water.

If a small amount of the notified polymer enters the aquatic environment, it is likely to be immobilised through adsorption onto soil particles and sediments. Based on the diffused use pattern, method of packaging and low concentration of the notified polymer in the developer, its release to the environment is expected to be low and dispersed. Abiotic or slow biotic processes are expected to be largely responsible for the eventual degradation of the notified polymer.

9.2. Human health

9.2.1 Human health - effects assessment

The notified polymer was shown to be of low acute toxicity via the oral route in rats and gave a negative result in the bacterial mutagenicity test. No other toxicity data have been provided. The notifier states that the developer may cause irritation on contact with the eyes. Inhalation may cause respiratory tract irritation and coughing.

The notified polymer has low water solubility and a low vapour pressure, and hence has low bioavailability. It contains low levels of residual monomers. Therefore, the notified polymer is unlikely to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

Exposure to developers containing the notified polymer during transport of pre-packed cartridges or bottles should not occur except in the event of accidental spillage.

The notified polymer will be imported in pre-packed cartridges or bottles at <1%. Dermal and inhalation exposure of office workers to the notified polymer may occur when refilling spent cartridges and clearing paper jams from the printer or photocopier. However, the design of the cartridges is such that exposure to the notified polymer should be low.

Dermal and inhalation exposure of maintenance workers to the notified polymer is possible during routine maintenance and developer replenishment but is expected to be low due to the low concentration of the notified polymer in the developer. Due to their frequent exposure to developers, maintenance personnel should wear cotton or disposable gloves.

Overall, the risk of adverse health effects arising from exposure to the notified polymer is low due to its expected low toxicity, low concentration in developer and low potential for exposure. Nevertheless, due to the particulate nature of the developer, skin, eye and respiratory exposure should be avoided. Photocopiers and printers should be located in well-ventilated areas. The NOHSC exposure standard for nuisance dusts of 10 mg/m^3 TWA (NOHSC, 1995) must be maintained in the workplace. Australia has no exposure standard for respirable dust, however, the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV) of 3 mg/m^3 TWA is recommended (ACGIH, 2001).

The low concentration of the notified polymer in the developer, the limited contact to the developer when in use, the presence of adequate ventilation in the workplace and the use of disposable gloves by maintenance personnel would ensure that the occupational risk posed by the notified polymer is low when used as specified in the notification.

9.2.5. Public health – risk characterisation

There is low potential for public exposure to the notified polymer during transportation, handling and usage of the developer unless accidental spillage occurs. In view of its physical and chemical properties, its low proportion in the developer, and the pattern of package and usage of the developer, the notified polymer is unlikely to pose a significant hazard to public health.

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

10.1. Hazard classification

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

10.2. Environmental risk assessment

On the basis of the information provided on its proposed use pattern, the overall environmental hazard from the notified chemical is considered to be low.

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 No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

No special precautions are required for the notified polymer when used at low quantities as a developer in pre-packed bottles or cartridges for electrophotocopying machines or electrophotographic printers. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed for use of developers containing the notified polymer:

- Avoid contact with skin and eyes.

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

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

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

- A copy of the MSDS should be easily accessible to employees.

- 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 in accordance with the federal, state and local regulations.

Emergency procedures

- Spills/release of the notified polymer should be contained by sweeping onto paper and carefully transferring to a sealable waste container for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(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.

No additional secondary notification conditions are stipulated. However, the polymer contains a primary amine which may become cationic. If greater release to the aquatic compartment is proposed, a secondary notification with a full suite of aquatic toxicity studies may be 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.

Huntingdon Life Sciences Ltd. (2003a) ST975YN Physicochemical Properties. (Study No. CNN487/032505, 29 April 2003) Huntingdon Life Sciences Ltd., Cambridgeshire, UK (unpublished report submitted by notifier).

Huntingdon Life Sciences Ltd. (2003b) ST975YN Abiotic Degradation: Hydrolysis as a Function of pH (Preliminary Test). (Study No. CNN488/032504, 29 April 2003) Huntingdon Life Sciences Ltd., Cambridgeshire, UK (unpublished report submitted by notifier).

Huntingdon Life Sciences Ltd. (2003c) ST975YN Bacterial reverse mutation test. (Study No. CNN530/032571, 3 June 2003) Huntingdon Life Sciences Ltd., Cambridgeshire, UK (unpublished report submitted by notifier).

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for Summarising and Evaluating the Environmental Aspects of Pesticides. National Institute of Public Health and Environmental Protection, Bilthoven, The Netherlands. Report No. 679101022.

Nabholz JV, Miller P and Zeeman M (1993) Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In: Landis WG, Hughes JS & Lewis MA ed Environmental Toxicology and Risk Assessment, ASTM STP 1179, American Society for Testing and Materials, Philadelphia, PA.

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

NOHSC (1995); 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.

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

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

Safepharm Laboratories Limited. (2003) ST975YN Acute oral toxicity in the rat- Acute toxic class method. (Study No. 897/302, 27 June 2003) Safepharm Laboratories Limited, Derbyshire, UK (unpublished report submitted by notifier).