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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NT-16

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

NT-16

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty Ltd
1 Thomas Holt Drive
North Ryde NSW 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

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
Abiotic degradation
Flash point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US-EPA (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NT-16

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 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 electrophoto-copying machines and electrophotographic printers. The coated carrier containing the notified polymer (30-100µm particle size) transfers the toner during the copier and printer opreations.

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 0.47 to 1.25 L sealed cartridges or bottles containing between 207-621 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 electrophoto-copying 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 (30-100µm). 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
Release of the developer containing the notified polymer to the environment is not expected under normal use as the bottles and cartridges are designed to prevent leakage. However, if leakage does occur, the developer will be contained and presumably disposed of in landfill. Environmental exposure will result from and discarded cartridges as well as the possibility of accidental leakage of

the cartridges during use.

In case of cartridge type container, developer residues contained in the empty cartridges and bottles are expected to be about 100% of the import volume and to remain in the containers. In case of bottle type container, developer residues contained in the empty bottles are expected to be 0%, but all developer residues remain in the machines. Cartridges and bottles may be collected by recovery systems (and recycled or reused) or disposed of to landfill. Waste developer collected in plastic bags from the waste reservoirs will be disposed of in rubbish. The total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated.

5.5. Disposal

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

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. 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. The waste developer could be considered as powder of metal oxides and plastic powder. Disposal should be subject to federal, state or local laws. Used bottle or cartridge containing 100% of the initial amount of the developer will be collected by recovery system for recycle or reuse, or sent to landfill for disposal.

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 (2001)

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 (2001)

Density 1290 kg/m^3 at 24ºC

METHOD	OECD TG 109 Density of Liquids and Solids.
TEST FACILITY	Huntingdon Life Sciences Ltd (2001)

Vapour Pressure 1.1 x 10^{-7} kPa at 25ºC

METHOD	OECD TG 104 Vapour Pressure.
Remarks	A vapour pressure balance and linear regression analysis was used to calculate vapour pressure at 25°C. The low value determined indicates that the notified polymer is classified as being very slightly volatile.
TEST FACILITY	Huntingdon Life Sciences Ltd (2001)

Water Extractivity 33-249 mgC/L at 20°C

METHOD	OECD TG 120 Water Extractivity.
Remarks	Analytical Method: TOC analyser A preliminary estimate of the solubility indicated the solubility was <1 mg/L. In a subsequent extractivity test the carbon content of the water phase was determined.

After filtering the carbon was found to be between 33-249 mgC/L depending on loading. The higher carbon content observed at higher dose levels. The variation in the measured carbon content results from the dissolution in increasing amounts of impurities with increasing loading. The polymer itself is likely to have low solubility.

TEST FACILITY Huntingdon Life Sciences Ltd (2001)

Hydrolysis as a Function of pH Not determined

Remarks Hydrolysis as a function of pH was not determined for this notification due to the notified polymer's low water solubility. The polymer does not contain any functionalities which are generally considered to be hydrolysable.

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.

Adsorption/Desorption log K_{oc} = >3.6

METHOD QSAR

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

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

Where S is the water solubility in mg/L (taken to be <1 mg/L from Preliminary water solubility test)

TEST FACILITY Huntingdon Life Sciences Ltd (2001)

Dissociation Constant Not determined

Remarks A dissociation constant was not determined due to the notified polymer's low water solubility. The polymer contains several nitrogen atoms which are expected to display typical basicity.

Particle Size 0.3% by mass smaller than 75µm
30-100µm (coated carrier containing the notified polymer)

METHOD OECD TG 110 Particle Size Distribution

Range (µm)	*Mass (%)*
>400	85.7
400 – 125	13.5
125-75	0.5
75-30	0.2
30-10	0.1
<10	0

TEST FACILITY Huntingdon Life Sciences Ltd (2001)

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 (2001)

Autoignition Temperature >400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

TEST FACILITY Huntingdon Life Sciences Ltd (2001)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY Huntingdon Life Sciences Ltd (2001)

Reactivity

Remarks Stable under normal conditions of use.

ADDITIONAL TESTS

Oxidizing Properties Non-oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
TEST FACILITY Huntingdon Life Sciences Ltd (2001)

7. TOXICOLOGICAL INVESTIGATIONS

A bacterial reverse mutation study was submitted for the notified polymer. No other toxicity data for the notified polymer were submitted.

7.1 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
Metabolic Activation System	Rat liver S9 fraction from animals pretreated with Phenobarbital and 5,6-benzoflavon
Concentration Range in Main Test	a) Test 1, with and without metabolic activation: 19.5, 78.1, 312.5, 1250, and 5000 µg/plate. b) Test 2, with and without metabolic activation: 312.5, 625, 1250, 2500, and 5000 µg/plate c) Test 3, without metabolic activation (TA100 only): 78.1, 156.3, 312.5, 625, 1250, 2500 and 5000 µg/plate
Vehicle	Dimethylsulfoxide
Remarks - Method	Two separate tests were performed in duplicate. A third test was conducted on TA100 without metabolic activation because of the growth inhibition present in the second experiment.
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. In the second test, growth inhibition was observed in TA100 at 312.5 µg/plate and above (without metabolic activation), and at 5000 µg/plate (with metabolic activation).
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Chemicals Safety Division, Canon Inc. (2000)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release to the environment of the developer containing the notified polymer is not expected under normal use as the cartridges and bottles are designed to prevent leakage. However, if leakage does occur, the developer will be contained and presumably disposed of in landfill. Environmental exposure will result from discarded containers (cartridges and bottles) and waste developer. In addition, environmental exposure may occur as a result of accidental leakage of the containers during use.

In case of cartridge type container, developer residues contained in the empty cartridges and bottles are expected to be about 100% of the import volume and to remain within the containers. In case of bottle type container, developer residues contained in the empty bottles are expected to be about 0%, but all the developer residues remain in the machine. Waste developer collected in plastic bags from the waste reservoirs will be disposed of in rubbish and end up in landfill. The total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated.

Polydimethylsiloxanes are unstable in landfill and on dry sediments (Hamelink, 1992; Lehmann *et al*, 1994a and 1994b) because under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. However, when released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink 1992).

9.1.2. Environment – effects assessment

No ecotoxicity data were submitted for the notified polymer. There will be limited release to the aquatic compartment.

9.1.3. Environment – risk characterisation

The notified polymer will enter environmental compartments by direct release from discarded cartridges, bottles and plastic bags at landfill sites. Based on the import volume, method of packaging and low concentration of the notified polymer in the developer, 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 will partition to the supernatant water which is released to the sewer.

As a consequence of its low water solubility, the notified polymer is likely to be immobilised through adsorption onto soil particles and sediments. Polydimethylsiloxanes are unstable in landfill and on dry sediments (Hamelink, 1992; Lehmann *et al*, 1994a and 1994b) because under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. However, when released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink, 1992). Therefore in landfill, the notified polymer would eventually degrade and as such poses little risk to the environment.

Releases to the sewer will be low because very little of the notified polymer is expected to reach water and partition to supernatant water. Furthermore, the substance is not expected to bioaccumulate due to its limited release to water.

9.2. Human health

9.2.1 Human health - effects assessment

The notified polymer gave a negative result in the bacterial mutagenicity test. No other toxicity data have been provided for the notified polymer. The notifier states that the developer may cause irritation on contact with the eyes. Inhalation may cause respiratory tract irritation and coughing. No component of the developer is listed as a human carcinogen or a potential carcinogen.

The notified polymer has low water solubility and a low vapour pressure, and hence has low bioavailability. It contains low residual monomers. Therefore, the notified polymer is unlikely to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

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. Photocopies 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 polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental hazard of the notified polymer is expected 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 for the developer containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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, 1994b). 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 electrophoto-copying 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 landfill.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie. sweep onto paper and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

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;
- the molecular weight of the polymer is less than 1000 and the polymer contains nitrogen atoms which may become cationic. If the import volume exceeds 1 tonne per year, a full standard notification should be submitted.

(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.

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.

Chemicals Safety Division (2000) Report of Mutagenicity Test Using Microorganisms (Report No. 632). Tokyo, Japan, Chemical Products Quality Assurance Center, Canon Inc (Unpublished report submitted by Canon Australia Pty Ltd).

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