File No PLC/550

June 2005

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

NT-35

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.

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Canon Australia Pty. Ltd. (ABN: 66005002951)
1 Thomas Holt Drive
North Ryde, NSW, 2113

NOTIFICATION CATEGORY
Polymer of Low Concern

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

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers, Import Volume, and Site of Manufacture/Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NT-35

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
None.	Moderate/High Concern	

Criterion	*Criterion met (yes/no/not applicable)*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Importation as a <1% component of developer in cartridges or plastic bottles.

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

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

USE
Coating resin for carrier particles at <1% in developer for electrophoto-copying machines.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The developer containing <1% notified polymer will be imported, distributed and supplied to consumers contained in a sealed cartridge or bottle packaged in cardboard cartons.

The developer is mainly used in photocopiers in offices. To refill the developer, the developer bottle is firmly fitted into the copying machine and the shutter opened. To change the cartridge, the seal tape is removed and the cartridge is placed into the copying machine or printer. The developer bottle and cartridge are designed not to release the developer until the shutter is opened or seal tape is removed. Used cartridges may be disposed of to landfill, or collected and exported for recycling.

During the copying or printing operation, the developer is transferred to the waste toner box, which is replaced periodically and disposed of to landfill.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

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 polymer may occur when replacing spent cartridges and clearing paper jams from the photocopier. However, the design of the cartridge makes exposure unlikely. Replacing the waste toner box involves removing the waste toner pipe and closing the lid. Exposure is not expected to occur.

6.2. Summary of Public Exposure

The notified polymer will not be available to the public. Members of the public may come into contact with products containing the notified polymer.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

The notified polymer is a minor ingredient (<1%) in developers for electrophoto-copying machines or printers. The notified polymer is imported in sealed plastic bottles and cartridges, and does not undergo any reformulation within Australia. As the notified polymer is not a toner component, it is not consumed as toner nor is printed onto paper. Therefore, all imported notified polymer remains in the cartridge or in the copying or printing machine. Therefore, aside from accidental container breaches, the notified polymer is unlikely to be released into the environment under the normal use and handling of the developer product.

6.3.2. Environmental Fate

The fate of the notified polymer is linked to that of the imported plastic bottles and cartridges. Spent cartridges may be collected by recovery systems and may be recycled or reused. Spent cartridges and bottles that are not recycled are likely to be sent to landfill. The notified polymer is expected to remain within these containers and eventually degrade through abiotic and biotic processes.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White or light yellow clear powder
Softening Point	140 °C
Density	1320 kg/m^3
Water Extractivity	0.1 and 0.5 mgC/l at 0.1% and 1% (w/v) respectively
Particle Size	10-125 μm: 10.7% <10 μm: 0%
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

Studies for the following toxicological end-points were submitted:

Endpoint	*Result*	*Classified?*	*Effects Observed?*
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity	no	no
Rabbit, skin irritation	non-irritating	no	no
Rabbit, eye irritation	slightly irritating	no	yes
Genotoxicity – bacterial reverse mutation	non mutagenic	no	no

8.1.1. Discussion of observed effects

Exposure to the eye of rats resulted in mild, early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, discharge and chemosis. Mean redness of the conjunctivae over 24, 48 and 72 hours for all three animals was 0.67. All other scores were 0 over this period.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This was confirmed by toxicological reports submitted by the notifier.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

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

10. RISK ASSESSMENT

10.1. Environment

While environmental exposure is limited during toner use, the total import volume of the notified polymer will ultimately be disposed of in landfill. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer bound within the spent cartridges and bottles.

The notified polymer is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low, based on low exposure, and low hazard. 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, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

10.3. Public Health

As there will be no exposure of the public to the notified polymer the risk to the public from exposure to the notified polymer is considered low.

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

11.1. Environmental Risk Assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is no concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is negligible concern to public health when used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. 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.
- 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 to landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by physical containment, collection and subsequent disposal to secure landfill or by thermal decomposition in high temperature incinerators.

AICS ANNOTATION

- The notified chemical has been flagged for AICS annotation after the 5-year confidentiality period, due to concerns about persistent and bioaccumulative breakdown products.

13.1. 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 subsection 64(1) of the Act; if
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria; or
- any further information is obtained on the breakdown products of the polymer; or
- the amount of the polymer being introduced is increased above one tonne; or
- the polymer is used in a way that would increase environmental or public exposure above the levels described in this assessment.

or

(2) Under subsection 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.