

File No PLC/708

2 July 2007

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

NT-39

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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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:

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**Director
NICNAS**

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Hewlett-Packard Australia Pty Ltd (ABN 74 004 394 763)
31-41 Joseph Street, Blackburn VIC 3130

Canon Australia Pty Ltd (ABN 66 005 002 951)
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 identity and details of polymer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:
Melting Point/Glass Transition Temperature
Dissociation constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NT-39

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	>1000
% of Low MW Species < 1000	< 5
% of Low MW Species < 500	< 5

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
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. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light brown powder
Melting Point/Glass Transition Temp	Polymer degrades at > 128°C Glass transition temperature: approximately 66°C
Density	1140 kg/m ³ at 20.1°C
Water Solubility	High/low concentration at each temperature/pH: 33.55 and 1.05 × 10 ⁻³ g/L (at 37°C/pH 2.0) 25.53 and 1.90 × 10 ⁻³ g/L (at 20°C/pH 7.0) 22.56 and 1.71 × 10 ⁻³ g/L (at 37°C/pH 9.0) Gravimetric analysis: 5 g and 0.5 g of the notified polymer were suspended in 500 ml of aqueous solutions, adjusted to pH 2.0, 7.0 and 9.0 and shaken for 24 hours at 20°C and at 37°C (pH 2.0 and pH 9.0) and filtered.
Dissociation Constant	pKa 4.6 (estimate based on molecular structure)
Particle Size	The mass median diameter is 327.1 µm. The range of particle size distribution is from approximately 0.5 to 2000 µm.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10-100	10-100	10-100	10-100	10-100

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported into Australia as an ingredient (40-60%) of toner in sealed printer cartridge products (ranging in size from 80g to 1600g), and the products are distributed to the consumers.

Reformulation/manufacture processes

All notified polymer will be imported into Australia as an ingredient of toner in printer cartridge products and distributed to the customers. Therefore, manufacturing, processing, and/or reformulation are not performed in Australia. The user will open a package of product, and insert the cartridge into a printer. The toner is fixed as an image on the printed paper, by heat, and outputted from the printer. The empty cartridge is taken out from the printer and exchanged to a new cartridge.

Use

An ingredient of toner for Electro-Photographic printer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and inhalation exposure of office workers and maintenance engineers to up to 60% of the notified polymer could potentially occur when replacing spent cartridges and clearing paper jams from the printer. However, the respirable (mean particle size < 10 µm) proportion of the polymer dust generated during use is low (<1%), and the design of the sealed cartridges should ensure leakage is unlikely and as such, exposure to the notified polymer should be low. Once the toner dries, the polymer would be trapped in the printed paper, and therefore dermal exposure to the notified polymer from contact with the dried toner is not expected.

PUBLIC EXPOSURE

The scenarios by which the public may be exposed to the notified polymer would involve home use of printers, and are similar to those for office workers. However, it is expected that the public will be using the printer less often than office workers.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	no	OECD TG 423
4. Rabbit, skin irritation	non-irritating	no	no	OECD TG 404
5. Rabbit, eye irritation	non-irritating	no	yes*	OECD TG 405
6. Skin sensitisation - non-adjuvant test	no evidence of sensitisation.	no	no	Buehler test
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	Similar to OECD TG 471

*The instillation of notified polymer into the eye resulted in mild, early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, discharge and chemosis. These effects were reversible and were no longer evident 72 hours after treatment, the end of the observation period for all animals.

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer.

PUBLIC HEALTH

The risk to public health presented by the notified polymer is expected to be low due to its intrinsic low toxicity, low concentration in toner and low potential for exposure. Nevertheless, due to the particulate nature of the toner, skin, eye and respiratory exposure should be avoided. Photocopiers and printers should be located in well-ventilated areas.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the toner is not expected during importation, storage and transportation. Spillage during a transport accident is the most likely reason for environmental release. In such an event, individual container capacity and container specifications would limit the extent of release since each toner cartridge, containing 80-1600 grams of toner, is designed to prevent leakage. If leakage does occur, the toner will be collected and sent to landfill for disposal.

Used cartridges containing up to 10% of toner (estimated to be up to 10000 kg per annum) will be sent to landfill for disposal. Residues contained in the empty bottles/cartridges are expected to remain within these containers, although release could occur from deterioration of the cartridge while in the landfill waste. Alternatively, the spent cartridges will be collected by the recovery system and will be exported to abroad for reprocessing without being processed in Australia.

Toner containing the notified polymer will be applied to paper products. Some waste paper could be disposed of directly to landfill with the notified polymer strongly bound to the paper. In addition to landfill, some printed paper will enter the paper recycling process.

ENVIRONMENTAL FATE

The notified polymer contains groups in the backbone/side chain that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse or settle to sediment. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon.

7.2. Environmental Hazard Characterisation

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This does not apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

7.3. Environmental Risk Assessment

While environmental exposure is limited during toner use, the total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer bound into the toner matrix within cartridges and on paper products. The used toner would be expected to remain within the container unless breached. On paper the notified polymer will interact with other components to form a stable polymer matrix and, once dry, is expected to be immobile and pose little risk to the environment.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

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.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

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

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. 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 and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.
- 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 incineration or to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

10.1. 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

- (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.