

File No PLC/704

May 2007

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

FULL PUBLIC REPORT

NT-40

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**Polymer in NT-40****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANTS

Canon Australia Pty Ltd (ABN: 66 005 002 951)
1 Thomas Holt Drive
North Ryde NSW 2113

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

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/Impurities.

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

USA, 2005

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NT-40

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000

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 solid
Glass Transition Temp	77°C
Density	1179 kg/m ³ at 19.8°C
Water Solubility	<0.088 mg/L at 37°C/pH 2.0 <0.088 mg/L at 20°C/pH 7.0 <0.110 mg/L at 37°C/pH 9.0, as determined by HPLC using OECD TG 105 and OECD TG 120.
Dissociation Constant	Could not be accurately determined using OECD TG 112. The notified polymer contains limited anionic functionality typical of polyesters.
Particle Size	478.3µm MMD <100 µm 7.9% <10 µm 0.52%
Reactivity	Stable under normal environmental conditions. While the notified polymer has hydrolysable functionality, little hydrolysis was observed in the above water solubility test.
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>	<1	1-10	1-10	1-10	1-10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

Imported as a component (up to 10%) in printing ink in sealed toner cartridges and bottles.

Reformulation/manufacture processes

No reformulation or manufacturing processes will occur in Australia.

Use

The printing ink cartridges and bottles containing the notified polymer (up to 10%) are used in office and consumer printing.

. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and inhalation exposure to the notified polymer may occur when refilling/replacing spent cartridges or when clearing paper jams from the printer or photocopier. However, the concentration of the notified polymer in the ink is low, and the design of the cartridges is such that exposure to the notified polymer should be low. Once the ink dries, the polymer would be trapped in the printed paper, and therefore dermal exposure to the notified polymer from contact with the dried ink 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 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 at 100% concentration.

<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	yes	OECD TG 423
4. Rabbit, skin irritation	non-irritating	no	no	OECD TG 404
5. Rabbit, eye irritation	slightly irritating	no	yes	OECD TG 405
6. Skin sensitisation - LLNA.	no evidence of sensitisation.	no	no	OECD TG 429 (LLNA)
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	Similar to OECD TG 471 with some slight protocol deviations.

Acute Oral Toxicity

All animals showed mild clinical signs of toxicity that included slightly ruffled fur alone or combined with slight sedation on the day of treatment at the 30 minute observation and persisted up to 3 hours in 3/6 animals, up to 2 days in 2/6 animals and up to 3 days in 1/6 animals. No other clinical signs were noted throughout the remainder of the study.

Eye Irritation

The notified polymer cause early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, discharge and chemosis. Conjunctival chemosis of grade 1 was observed in all animals at the 1 hour observation period. Conjunctival redness of grade 1 and 2 was observed 1 hour after treatment in 1/3 and 2/3 animals respectively and persisted in 2/3 animals at the 24 and 48 hour observation (grade 1).

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 hazard of the polymer.

PUBLIC HEALTH

The risk to public health presented by the notified polymer is expected to be low due to its low toxicity, low concentration in the ink and low potential for exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the notified polymer is summarised in the following table.

<i>Source of release</i>	<i>% Volume</i>	<i>Released to / Fate</i>
Residual notified polymer in cartridges	≤10%	Incinerated at Cartridge Recycling Facilities
Notified polymer on recycled printed paper	≤60%	Sewer
Notified polymer on printed paper	≥30%	Landfill

ENVIRONMENTAL FATE

Notified polymer disposed of to landfill is expected to associate with soil and organic material and should be relatively immobile within the landfill environment. Over time, the notified polymer is expected to degrade by biotic and abiotic means to form simple organic compounds.

Notified polymer on printed paper sent for recycling, which is not removed during recycling is expected to be released via the trade sewer where a major proportion may be absorbed to sludge due to low solubility. Any remaining polymer that enters the aquatic environment is expected to eventually associate with soil and sediments, and overtime degrade via biotic and abiotic processes to form simple organic compounds.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. 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 should not apply to the notified polymer. Further, 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

The notified polymer is imported into Australia in recyclable print cartridges. During recycling, it is expected that up to 10% residual notified polymer will be destroyed by incineration. Following use, printed paper may be disposed of directly to landfill, or recycled. Assuming that all printed paper is sent for recycling, up to 60% of the total volume of notified polymer may be released to the aquatic environment via the trade sewer. The remainder is expected to be disposed of to landfill.

Using a worst case scenario without removal in sewage treatment plants, the following PEC has been calculated.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	60%	
Annual quantity of chemical released to sewer	6,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	16.44	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	4.01	µg/L
PEC - Ocean:	0.40	µg/L

As no ecotoxicity data are available, a PNEC and resultant Risk Quotient (Q) are unable to be calculated. However, given the low volume and diffuse release pattern, there should be an adequate safety margin and the overall environmental risk is expected to be acceptable.

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.

- 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.