

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

POLYMER OF LOW CONCERN PUBLIC REPORT

NT-80

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment and Energy.

This 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: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, 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**

January 2018

Table of Contents

SUMMARY	2
CONCLUSIONS AND REGULATORY OBLIGATIONS	2
ASSESSMENT DETAILS.....	4
1. APPLICANT AND NOTIFICATION DETAILS.....	4
2. IDENTITY OF POLYMER.....	4
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION.....	5
6. HUMAN HEALTH RISK ASSESSMENT	5
7. ENVIRONMENTAL RISK ASSESSMENT.....	6
BIBLIOGRAPHY.....	7

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1463	Canon Australia Pty Ltd. HP PPS Australia Pty Ltd.	NT-80	No	≤ 5 tonnes per annum	Component of toner

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- Water insoluble high molecular weight polymers used in the respirable size range (< 10 µm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure.
- If aerosols are formed during the use of the notified polymer, engineering controls and respiratory protection should be used to prevent inhalation exposure.
- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

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

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

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

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
 - further information becomes available on the sensitisation and/or irritation potential of the notified polymer
 - the notified polymer is introduced at concentrations above 5% and/or is to be reformulatedor
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of toner, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDS of the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Canon Australia Pty Ltd. (ABN: 66 005 002 951)
Building A, 5 Talavera Rd
MACQUARIE PARK NSW 2113

HP PPS Australia Pty Ltd (ABN: 16 603 480 628)
Level 5, 1 Homebush Bay Drive
RHODES NSW 2138

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, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

NT-80

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</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	White powder
Melting Point/Glass Transition Temp	102 ~ 126 °C
Density	1,050 kg/m ³ at 20 °C
Water Solubility	< 1x10 ⁻³ g TOC/L at 20 °C
Dissociation Constant	Not determined; contains anionic functionalities with a typical pKa ~ 4 and is expected to be ionised in the environmental pH range (4 - 9).
Particle Size	40.5% w/w < 100 µm 5.99% w/w < 10 µm 1.87% w/w < 5.5 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

Year	1	2	3	4	5
Tonnes	2	5	5	5	5

Use

The notified polymer will not be manufactured in Australia. It will be imported in finished toner cartridges for use in commercial, office and home printers and photocopying machines. The final concentration of the notified polymer in toners will be < 5%.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	Result	Effects Observed?	Test Guideline
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	OECD TG 420
2. Rabbit, skin irritation	non-irritating	no	OECD TG 404
3. Rabbit, eye irritation	mild irritant	yes	OECD TG 405
4. Skin sensitisation	no evidence of sensitisation.	yes	OECD TG 429 (LLNA)
5. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

In a rabbit eye irritation test, moderate conjunctival effects were observed in both test animals at 1, 24 and 48 hours after treatment with test substance which contained the notified polymer at 100% concentration in powder form. The treated eyes of both test animals appeared normal in observation at 72 hours post treatment. The test substance produced a maximum group mean irritation score of 10.0 suggesting the test substance to be a mild irritant. The irritation effects observed were not sufficient for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*.

In a Local Lymph Node Assay in mice testing at concentrations of 5, 10 and 25% w/w in acetone/olive oil 4:1 there was fur loss observed at days 3 to 6 at the 25% concentration level. The Stimulation index was under 3 for all test concentrations and the chemical was considered a non-sensitizer under test conditions.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

The particle size of the notified polymer indicates that a portion will be respirable (< 10 µm). The notified polymer is water soluble and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The expected use of dust masks and good general ventilation when replacing the toners containing the notified polymer by maintenance workers should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading. Due to less frequent replacement of the toner cartridges by general consumers and the process being carried out in rooms with good general ventilation, lung overloading from inhalation exposure is not expected.

The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted for the notified polymer. Anionic polymers are generally of low toxicity to fish and daphnia, however they can be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. However, this does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

The notified polymer will be imported in finished toner cartridges and will not be reformulated or repackaged in Australia. The toner cartridges containing the notified polymer will be used in commercial, office and home printers and photocopying machines. Accidental spills of the notified polymer during import, transport, storage and use are expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. The empty cartridges containing residues of the notified polymer will be either recycled or sent to an authorised facility for safe disposal.

Most of the notified polymer is expected to share the fate of the paper on which it is applied to, to be either subjected for paper recycling or disposed of to landfill. According to the recent Australian National Waste Report (DoEE and Blue Environment Ltd., 2016), 60% of the waste paper treated with the notified polymer is expected to be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The notified polymer discharged to wastewater from paper recycling processes is expected to be effectively removed through adsorption to sludge or by flocculation at wastewater treatment plants (US EPA, 2013; Boethling and Nabholz, 1997), and only a small proportion of the notified polymer may be released to surface waters after treatment processes.

The most toxic anionic polymers to algae known, have EC50 values of > 1 mg/L (Boethling and Nabholz, 1997). As this is likely to be the most sensitive species, an assessment factor of 100 is used to estimate the Predicted No-Effect Concentration (PNEC). Therefore the estimated PNEC is likely to be > 10 µg/L.

With 60% release of the notified polymer into the sewer systems through paper recycling processes and no removal within sewage treatment plants as the worst case scenario, the conservative predicted environmental concentration (PEC) in sewage effluent on a nationwide basis over 260 working days per year is calculated to be 2.37 µg/L, which is below the estimated PNEC. Thus, release of the notified polymer during the recycling and deinking processes is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment.

Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. Based on its limited water solubility and high molecular weight, the notified polymer is expected to have low mobility in landfill and soil (US EPA, 2013). The notified polymer is neither expected to be bioaccumulative given its high molecular weight and it contains no significant percentage of low molecular weight constituents. In landfill, soil and water, the notified polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water and oxides of carbon.

Therefore, based on its assumed low hazard and assessed use pattern in toner, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

Department of the Environment and Energy (DoEE) and Blue Environment Pty Ltd (2016) Australian National Waste Report 2016. Canberra, Australia.

US EPA (2013) Interpretive Assistance Document for Assessment of Polymers – Sustainable Futures Summary Assessment, US Environmental Protection Agency,
https://www.epa.gov/sites/production/files/2015-05/documents/06-iad_polymers_june2013.pdf.