

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

POLYMER OF LOW CONCERN PUBLIC REPORT

CIM-59

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:

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**Director
NICNAS**

August 2019

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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/1556	Canon Australia Pty Ltd	CIM-59	No	< 1 tonne per annum	Component of inkjet printing ink

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

- 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.
- If aerosols are formed during the use of the notified polymer, engineering controls and/or respiratory protection should be used to prevent inhalation exposure.

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.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of inkjet printing ink, 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 and products containing the notified polymer were 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)
5 Talavera Road
MACQUARIE NSW 2113

Exempt Information (Section 75 of the Act)

Data items and details exempt from publication include: chemical name, other names, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

CIM-59

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 g/mol

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 to yellow solid
Melting Point/Glass Transition Temperature	Not determined
Density	Not determined
Water Solubility	Soluble
Dissociation Constant	Contains anionic functionalities which are expected to dissociate in the environmental pH range of 4-9
Particle Size	Not determined
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>
Tonnes	< 1	< 1	< 1	< 1	< 1

Use

The notified polymer will be used as a component ($\leq 10\%$) of an aqueous ink formulation in inkjet cartridges (2.5 mL – 2.6 L) or ink bottles/containers (50 mL – 20 L). No manufacture, reformulation or repackaging of the ink products will occur in Australia. The inks containing the notified polymer will be used in inkjet printers for commercial, office and consumer use for printing on paper.

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.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed</i>	<i>Test Guideline</i>
*Acute oral toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity	no	OECD TG 420
*Mutagenicity – bacterial reverse mutation (pre-incubation method)	non mutagenic	no	Similar to OECD TG 471

* Molecular weight of the material tested was lower than that of the notified polymer.

All results were indicative of low hazard.

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 notified polymer is water soluble with high molecular weight 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 levels 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. Significant inhalation exposure is not expected from the proposed use of the notified polymer.

Given the expected low hazard, the risk of the notified polymer to occupational and public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to 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, leading to chelation of essential nutrients (Boethling & Nabholz, 1997). Parts of the notified polymer contain this polymer backbone structure. However, the notified polymer contains functionalities that dilute the chelating effect, which would result in significantly reduced toxicity to algae.

The notified polymer will be imported as a component of an aqueous ink formulation in inkjet cartridges or ink bottles/containers. No manufacture, reformulation or repackaging of the ink products will occur in Australia. The inks containing the notified polymer will be used in inkjet printers for commercial, office and consumer use for printing on paper. Accidental spills of the ink containing the notified polymer during import, transport, storage and use only occur if the packaging is breached. These spills, estimated by the notifier to account for up to 0.5% of the import volume of the notified polymer, are expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. The notifier estimates that empty cartridges contain residues of the notified polymer up to 1% of the import volume which are expected to be sent to landfill for disposal.

Most of the notified polymer is expected to share the fate of the paper to which it has been applied, either subjected to paper recycling processes or being disposed of to landfill at the end of their useful lives. According to the recent Australian National Waste Report (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. Based on its high molecular weight, 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.

With 60% release of the notified polymer into the sewer systems through paper recycling processes and no removal within wastewater 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 0.47 µg/L [$0.6 \times 1,000 \text{ kg/year} \div 260 \text{ days/year} \div (24.386 \text{ million persons} \times 200 \text{ L/person/day})$]. 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 may be sent to landfill for disposal or agricultural land for remediation. Based on its high molecular weight, the notified polymer is expected to have low mobility in landfill and soil. 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 and nitrogen and salts.

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

BIBLIOGRAPHY

Blue Environment Pty Ltd (2016) Australian National Waste Report 2016. Canberra, Australia.

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.

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.