File No PLC/1473

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

NT-83

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

February 2018

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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/1473	Canon Australia Pty Ltd	NT-83	No	≤ 200 tonnes per annum	Component of a toner for photocopiers and printers.

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

- 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 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 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 a toner for photocopiers and printers, 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, The Park Estate, 5 Talavera Road
MACQUARIE PARK NSW 2113

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-83

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 g/mol

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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 flakes
Melting Point/Glass Transition Temperature	100 - 135 °C
Density	1.06 x 10^3 kg/m^3 at 20.0 ± 0.5 °C
Water Solubility	< 2 x 10^{-4} g/L at 20.0 ± 0.5 °C
Dissociation Constant	Not determined due to low water solubility. The notified polymer contains dissociable functionalities, and is expected to dissociate in the environmental pH range (4-9).
Particle Size	<100 µm 12.6 % w/w <10 µm 2.43 % w/w <5.5 µm 0.56 % w/w
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	10-30	20-100	20-100	20-100	50-200

Use
The notified polymer will be used as a component of a toner (0.1-20%) for photocopier machines or printers that will be used by workers and the public. No manufacture, reformulation or repackaging will occur in Australia.

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	slightly irritating	yes	OECD TG 405
4. Skin sensitisation – LLNA*	no evidence of sensitisation.	no	OECD TG 429 (LLNA)
5. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

*Tested up to 25% concentration.

All results were indicative of low hazard.

Given the assumed low hazard, confirmed for several endpoints by the studies listed above, the risk to human health posed by exposure to the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer is not considered to pose an unreasonable risk to the environment, based on its assumed slight to moderate toxicity to aquatic organisms, as well as a low likelihood of exposure.

No eco-toxicological data were submitted for the 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, leading to chelation of essential nutrients. The notified polymer contains functionality that dilutes the chelating effect, which results in significantly reduced toxicity to algae (Boethling & Nabholz, 1997). Since the notified polymer has a molecular weight > 1,000 Da with no significant percentage of low molecular weight constituents and also low water solubility, it is not expected to cross biological membranes and is therefore unlikely to bioaccumulate.

The notified polymer will be formulated overseas and imported as a pre-packaged component of toner. Accidental spills of the notified polymer during import, transport or storage are unlikely as the toner will be pre-packaged in a container that is designed to prevent leakage. Any leaks or spills that do occur during transport and storage are expected to be adsorbed onto a suitable material and collected for disposal of in accordance with local regulations. During use (copying or printing), toner will be transferred onto the paper and heat-fixed. Environmental releases could occur from sewage treatment

plants (STPs) via the recycling of paper on which the toner containing the notified polymer has been used.

The current Australian Waste Report estimates 60% of paper and cardboard in Australia are recycled (Pickin and Randell, 2017) over 260 days/year. During the recycling, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks from the fibres. Aqueous wastes are expected to be discharged to sewer and treated at sewage treatment plants (STP). The notified polymer is of high molecular weight and has slight water solubility. Hamilton & Sutcliff, (1997) found that polymers with such characteristics absorb to sludge in the STP, in amounts > 90%. This amount will be removed from the effluent and the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 9.5 µg/L [PECriver = 460 kg notified polymer/day × 0.1 (mitigation factor) ÷ (200 L/person/day × 24.4 million people) × 1 (dilution factor)].

The anionic polymers that are most toxic to algae are known to have EC50 values of > 1 mg/L (Boethling & Nabholz, 1997). As this is likely to be the most sensitive species an assessment factor of 100 is used to estimate the PNEC. Therefore, the PNEC is likely to be > 10 µg/L and hence the release of the notified polymer during the recycling and de-inking processes will not lead to eco-toxicologically significant concentrations in the aquatic environment.

The notifier has not estimated the total annual import volume of the notified polymer may remain as residues in empty containers. Used containers are likely to be re-used or recycled. Discarded containers and sludge waste from paper recycling with polymer residues are expected to be disposed of to landfill. Biotic and abiotic degradation will occur during landfill, but the notified polymer is not expected to be mobile, and as stated above, unlikely to bioaccumulate. In landfill, the notified polymer is expected to degrade by biotic and abiotic processes to form water and oxides of carbon.

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

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) 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.

Hamilton, J. D. and R. Sutcliffe (1997). Ecological assessment of polymers: strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold.

Pickin, J. and P. Randell (2017). Australian National Waste Report 2016, A report prepared for the Department of the Environment and Energy: 1-84.