File No PLC/1451

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

CIM-55

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

October 2017

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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/1451	Canon Australia Pty Ltd	CIM-55	No	≤ 100 tonnes 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

- 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;
- the notified polymer is introduced in solid form for reformulation in Australia;
- additional studies become available on the fate and ecotoxicity of the notified polymer in the nano-size range

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 a product 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)
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, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
CIM-55

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

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	Milk white solid
Melting Point/Glass Transition Temperature	Decomposed prior to melting
Density	Expected to be > 1,000 kg/m^3
Water Solubility	30 mg carbon/L at 20 °C (OECD TG 120)
Dissociation Constant	The notified polymer is a salt and is expected to ionise in the environmental pH range (4-9). pKa carboxylic acid is ~ 5.
Particle Size	~ 51-204 nm The notified polymer will be introduced in liquid printing inks.
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	1-10	10-30	30-50	50-70	70-100

Use
The notified polymer will be used as a component (≤ 18%) of an aqueous ink formulation in inkjet cartridges (2.5 mL-2.6L), ink bottles (50 mL-20L) or ink containers (50 mL – 20L). No manufacture, reformulation or repackaging will occur in Australia. The inks containing the notified polymer will be used in inkjet printers for commercial, office and consumer use. The public will use ink cartridges and ink bottles, but not ink containers.

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 > 2,000 mg/kg bw	yes*	OECD TG 420
2. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

* Mucous stool observed in 2/5 animals on Day 1 was attributed to the effects of the olive oil vehicle.

All results were indicative of low hazard.

The inks contain the notified polymer in dispersion (particle size ~51-204 nm) with < 86% of the notified polymer particle size within the nano-size range (< 100 nm). With the proposed form of introduction (liquid inks) and use, inhalation exposure to nano-size particles is not expected. After application of ink to paper substrate and curing, the notified polymer will be trapped in the polymer matrix and is not expected to be available for exposure as particles.

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

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. However, this is unlikely to 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 into Australia as a component of aqueous ink formulation in inkjet cartridges, ink bottles or containers and will not be reformulated or repackaged. The ink containing the notified polymer will only be used in fully automated inkjet printing processes. Following printing, the notified polymer is expected to be stable within an inert ink matrix on printed substrates once cured.

The inks contain the notified polymer in dispersion with approximately < 86 % of the notified polymer within nano-size range (particle size < 100 nm) based on provided particle size distribution measured by Nanotrac Wave (EX). Release of the nanomaterials from the inkjet cartridges is not expected to be significant during the printing processes (Danish Environmental Protection Agency, 2015).

Potential environmental release of the notified polymer during use is expected to be limited to residues in empty containers (expected to be ~ 1% of the annual import volume), spills and cleaning of printing equipment (expected to be ~0.5% of the annual import volume). These wastes are expected to be contained and disposed of to landfill.

Ink containing the notified polymer will be used on paper substrates. The notified polymer, bound within the dried ink matrix, will share the fate of the printed paper to be disposed of to landfill or subjected for paper recycling. It is assumed by the notifier that 50% of used paper will be disposed of to landfill and 50% of the used paper will be subject to paper recycling processes. 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 containing these agents are expected to be treated at an onsite wastewater treatment plant or be sent to the sewage treatment plant (STP). With 50% of the total import volume of the notified polymer being released into the sewer systems and no removal within STPs, the predicted environmental concentrations in sewage effluent on a nationwide basis over 260 working days per year is calculated to be 39.43 µg/L, which is well below the known EC50 for algae of the most toxic anionic polymers (EC50 > 1 mg/L). Therefore, the release of the notified polymer during the recycling and deinking processes will not lead to ecotoxicologically significant concentrations in the aquatic environment.

The notifier has indicated that the notified polymer may aggregate to > 100 nm size after it has been applied to the paper substrate. Furthermore, during deinking processes, the notified polymer may form larger size aggregates/agglomerates in the waste streams. For example, acrylic-based polymers such as the notified polymer containing particles in the nanoscale have been shown to aggregate under high ionic strength conditions often achieved during the deinking process (Hanus et al., 2001), and hence the notified polymer is expected to form aggregates during the paper recycling processes and partition to sludge during the wastewater treatment processes. Therefore, significant release of the notified polymer in nano-size range to the aquatic environment is not expected.

A significant proportion of the notified polymer will reach landfill as a result of disposal of used articles, sludge waste from recycling and residue in empty containers. In landfill, the notified polymer bound on the articles to which it is printed is not expected to be mobile and bioavailable in this form. In addition, the notified polymer in its aggregated form is not expected to cross biological membranes due to its high molecular weight, and is therefore not expected to bioaccumulate. In landfill the notified polymer is expected to slowly degrade to inorganic salts, water and oxides of carbon, and sulfur. Therefore, based on its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

The Danish Environmental Protection Agency (2015) Release of nanomaterials from ink and toner cartridges for printers. Environmental project No. 1784, Ministry of Environment and Food. The Danish Environmental Protection Agency

Hanus, L.H., Hartzler, R.U., and N.J. Wagner (2001) Electrolyte-induced aggregation of acrylic latex. 1. Dilute Particle Concentrations. Langmuir 17: 3136-3147.