File No PLC/1505

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

FS-493

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

September 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/1505	KYOCERA Document Solutions Australia	FS-493	No	≤ 3 tonnes per annum	Component of printing 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

- 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 printing 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 a product containing 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
KYOCERA Document Solutions Australia (ABN: 77 003 852 444)
Level 3
6 – 10 Talavera Road
NORTH RYDE 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)
FS-493

Molecular Weight
Number Average Molecular Weight (Mn) is > 10,000 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 powder.
Melting Point/Glass Transition Temperature	Not determined.
Density	1,050 kg/m^3 at 20 °C
Water Solubility	Insoluble
Dissociation Constant	pKa ≤ 2
Particle Size	Inhalable fraction (< 100 µm): 100% Respirable fraction (< 10 µm): 95.7% MMAD/MAD* = 1.81 µm
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

* MMAD = Mass Median Aerodynamic Diameter / MAD = Mean Aerodynamic Diameter

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 3	< 3	< 3	< 3	< 3

Use
The notified polymer will be used as a component of toner (at a concentration of < 1%) for use in commercial and domestic printers. The toner (containing the notified polymer) will be imported in sealed cartridges. No manufacture, reformulation or repackaging will occur in Australia.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. 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.

One of the notified polymer's constituents has a structural alert for corrosion. The constituent is not present on the Hazardous Chemical Information System (HCIS). The constituent is expected to be bound within the notified polymer and is not present as a residual impurity or monomer. The component is only present at a concentration of 0.5% in the notified polymer, and therefore at 0.005% in the product, and at this low concentration is not considered to pose a risk for irritant effects.

The particle size of the notified polymer is given as 0.3 – 12.6 μm. Based on the data submitted, it is estimated that < 95.7% of the notified polymer is expected to be respirable (< 10 μm). The notified polymer is insoluble enhancing the penetration of particles into the lower respiratory tract. However, based on the high molecular weight of the notified polymer it is not expected to be absorbed. Therefore if inhaled at low levels, the notified polymer is likely to be cleared through mucocillary action. 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 risk of inhalation exposure (and hence the risk of temporary lung overloading) to the notified polymer is expected to be reduced through the use of engineering controls and presence of good general ventilation in areas containing printing machines.

Domestic users may be exposed to the notified polymer when handling the toner cartridges and exposure to the notified polymer is expected to be similar to that of office workers.

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). 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 sealed toner cartridges and will not be reformulated or repackaged in Australia. The toner cartridges containing the notified polymer will be used in commercial and domestic printers. Accidental spills of the notified polymer during import, transport, storage and use only occur if the packaging is breached. These spills 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 0.5% 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 its 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 insolubility in water and 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 1.42 µg/L [0.6 × 3,000 kg/year ÷ 260 days/year ÷ (24.386 million persons × 200 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 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 not 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 sulphur.

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 aquatic 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.