

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

POLYMER OF LOW CONCERN PUBLIC REPORT

FLX-001A

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**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1536	Fuji Xerox Australia Pty Ltd	FLX-001A	No	≤ 15 tonnes per annum	Component of printing inks

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.
- 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

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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 a component of printing inks, 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 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

Fuji Xerox Australia Pty Ltd (ABN: 63 000 341 819)
8 Khartoum Road
MACQUARIE PARK NSW 2113

Exempt Information (Section 75 of the Act)

Data items and details exempt from publication include: 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

FLX-001A

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	Pale white dispersion (in water)
Melting Point/Glass Transition Temperature	Not determined. The polymer is not isolated from the solution
Density	~ 1,000 kg/m ³ at 20 °C
Water Solubility	Dispersible due to its surfactant properties
Dissociation Constant	Contains anionic functionalities with an estimated pKa of 4
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	< 10	< 15

Use

The notified polymer will not be manufactured or reformulated in Australia. The notified polymer will be imported as a component of finished aqueous inkjet printer ink at $\leq 10\%$ concentration. The ink containing the notified polymer will be used for commercial high volume colour printings on paper, such as magazines and newspapers, and will not be made available to the public.

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.

It is noted that the notified polymer is water-insoluble with a molecular weight $> 70,000$ g/mol. Inhalation of polymers with molecular weights $> 70,000$ g/mol has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>, accessed on 22 February 2019). If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. The notified polymer is a component of printing ink for commercial use only. Given the printing process is expected to be largely automated and enclosed with exhaust ventilation, and expected low vapour pressure of the notified polymer, inhalation exposure to the notified polymer is expected to be limited.

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.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. 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). The SDS for the product containing the notified polymer at $\leq 10\%$ concentration indicates that the product is practically non-toxic to aquatic species [L(E)C50 > 100 mg/L, to fish, daphnia and algae]. The notified polymer has a molecular weight of $> 10,000$ mg/mol with no significant percentage of low molecular weight constituents and has a low water solubility; therefore it is not expected to cross biological membranes and is unlikely to bioaccumulate.

The notified polymer will be imported as a pre-packaged component of inkjet printer ink. Accidental spills of the notified polymer during import, transport, storage or during use are unlikely as the ink will be pre-packaged in 20 L bag-in-box cartridges and the process (commercial high volume ink-jet printing) is essentially automated and enclosed. Any leaks or spills that do occur are expected to be adsorbed onto a suitable material and collected for disposal of in accordance with local regulations. After printing, the notified polymer will be fixed with other ink ingredients onto the substrate surface, from which there is limited potential for release.

Substrates to which the notified polymer will be bound will eventually be disposed of to landfill, or released to sewage treatment plants (STPs) through effluent from paper recycling (de-inking) processes. Discarded containers containing residues of the notified polymer are also expected to be disposed of to landfill or recycled. 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.

The de-inking process during the recycling of paper on which the toner containing the notified polymer has been used may lead to environmental release via STPs. The current Australian waste report estimates approximately 60% of paper and cardboard in Australia are recycled (Blue Environment Ltd., 2016). Under a worst-case scenario 60% of the notified polymer will be washed into sewers over 260 working days per year. Assuming no removal of the notified within STPs, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 7.10 µg/L [$PEC_{river} = 34.62 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 24.386 \text{ million people}) \times 1$ (dilution factor)]. The anionic polymers that are most toxic to algae are known to 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 was used to estimate the PNEC. Therefore, the PNEC is > 10 µg/L and hence the release of the notified polymer during the recycling and de-inking processes is not expected to lead to eco-toxicologically significant concentrations in the aquatic environment.

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

BIBLIOGRAPHY

Boethling, RS and 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.

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