File No PLC/838

September 2009

NATIONAL INDUSTRIAL POLYMERS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer SP-11

This Assessment has been compiled in accordance with the provisions of the *Industrial Polymers (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Polymers Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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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FULL PUBLIC REPORT

Polymer SP-11

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Fuji Xerox Australia Pty Ltd (ABN 63 000 341 819)

101 Waterloo Road

NORTH RYDE NSW 2113

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Polymer Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

NOTIFICATION IN OTHER COUNTRIES

Japan (2008)

South Korea (2008)

2. IDENTITY OF POLYMER

MARKETING NAME(S)

Polymer SP-11

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)

> 10,000 Da

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Confidential	High Concern	> 5000

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 POLYMER PROPERTIES

Appearance at 20°C and 101.3 kPa: White powder Melting Point/Melting Range 240 \pm 0.5°C

Density $1220 \text{ kg/m}^3 \text{ at } 21.7 \pm 0.5^{\circ}\text{C}$

Water Solubility 5.33 x 10⁻⁵ g/L (measured by column elution method)

Dissociation Constant pKa = 8.25 (calculated) Particle Size $87.3\% < 100 \mu m$ $2.41\% < 10 \mu m$

 $2.41\% < 10 \ \mu m$ $1.84\% < 5.5 \ \mu m$

Oxidising Properties Not predicted to be oxidising

Reactivity Stable under normal environmental conditions

Degradation Products None under normal conditions of use. The notified polymer contains

some hydrolysable functions. However, hydrolysis is unlikely to occur

in the environmental pH range of 4-9

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS

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

Use

The ink containing the notified polymer will be used at $\leq 10\%$ in inks for printer toners.

Mode of Introduction and Disposal

The notified polymer will be imported at $\leq 10\%$ in a finished toner formulation in sealed cartridges up to 1700 mL.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

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

Occupational Health and Safety Risk Assessment

The notified polymer is a high molecular weight, with low water solubility and a majority of particles (87.3%) in the inhalable range (< $100~\mu m$) and a small amount (2.41%) in the respirable range (< $10~\mu m$). These particles could impair lung function after repeated exposure. However, the notified polymer will only be imported in a toner formulation contained within sealed toner cartridges and release of airborne particulates is not anticipated during normal use.

The notified polymer is considered to present a low risk to the health of workers, based on its assumed low toxicity, low concentration in printer toner and low potential for exposure.

Public Health Risk Assessment

The toner cartridges containing the notified polymer will not be sold directly to the public. The public may experience dermal contact with printed paper containing the notified polymer. However, the notified polymer will be bound to the paper and is not expected to be available for exposure. The notified polymer is not expected to present an unacceptable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Risk Assessment

Environmental release is expected to be low as the notified polymer will be imported in sealed cartridges and printed onto paper. The notified polymer will become detached from the paper fibre during recycling, but because of the low water solubility will be removed with sludge during waste water treatment. Sludge, spillages, residues in cartridges and waste paper are expected to be disposed of to landfill, where the notified polymer will remain immobile and slowly degrade.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

• Specific engineering controls, work practices or personal protective equipment 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.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

• The notified polymer should be disposed of by incineration or to landfill.

Emergency procedures

• Spills and/or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

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 Polymers (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 Polymer 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 polymer form that does not meet the PLC criteria;
 - the notified polymer is introduced in powder form and not within a sealed cartridge;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of printer 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 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.

Material Safety Data Sheet

The MSDS of the notified polymer and the product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.