

File No PLC/868

November 2009

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

FULL PUBLIC REPORT

Polymer in Liosyzer EB10

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals 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 in Liosyzer EB10****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Toyo Ink Australia Pty Ltd (ABN 29 006 294 837)
 29 Garden Street
 Kilsyth VIC 3137

NOTIFICATION CATEGORY

Polymer of Low Concern

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 and Residual Monomers/Impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Japan and Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Liosyzer EB10

MOLECULAR WEIGHT (MW)

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

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Amine	High Concern	> 5,000

3. PLC CRITERIA JUSTIFICATION*Criterion*

Molecular Weight Requirements
 Functional Group Equivalent Weight (FGEW) Requirements
 Low Charge Density
 Approved Elements Only
 Stable Under Normal Conditions of Use
 Not Water Absorbing
 Not a Hazard Substance or Dangerous Good

Criterion met

Yes
 Yes
 Yes
 Yes
 Yes
 Yes
 Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White solid
Melting Point/Glass Transition Temp	Not determined, the notified polymer will be introduced in solution.
Density	Not determined, the notified polymer will be introduced in solution.
Water Solubility	0.16 – 7.8 x 10 ⁻³ g/L at 20°C A modified version of the flask method was used. The TOCs of the filtrates of the filtered samples were determined.
Hydrolysis as a function of pH	pH stability tests (pH 4 – 9) over 2 weeks indicated no significant changes in the weight-average molecular weight and the infrared spectral data of the notified polymer. The results were measured by GPC and FT-IR
Dissociation Constant	Not determined. Given the notified polymer contains a functional group likely to have a pKa >11, the polymer is not expected to be protonated at significant levels over the environmental pH range (4-9).
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	1	1

Use

The notified polymer acts as a binder, at a concentration of 3% in rotary press and offset lithographic printing inks. The formulated inks are used by printers for printing documents such as magazines and advertising paper.

There will be no manufacture or reformulation of the notified polymer within Australia.

At the printing sites, the finished inks containing the notified polymer will be added to the printing presses through an automated pumping system. The ink will be transferred into enclosed inking units and then transferred to the substrate by a system of rollers. The metering and application of the ink on the machine will be conducted automatically. The residual ink in the ink units will be transferred back to the original container by the use of a pumping system. Once the printing job has been completed, the parts of the printing press that are covered with ink will be wiped clean using rags and solvents.

Mode of Introduction and Disposal

The notified polymer will be imported by sea as finished ink products, at a concentration of 3%, typically in 1 L cartridges. From the port, the cartridges will be transported by road to the notifier's warehouse before being distributed to customers across Australia.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

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

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure from the finished ink product containing the notified polymer may potentially occur during the opening of the containers, transfer of the ink into the inking units and the cleaning of the printing press. However, exposure to significant amounts of the notified polymer will be limited because of the largely enclosed and automated processes, and the use of ventilation and extraction systems, as well as personal protective equipment (PPE) worn by workers. After application and once dried, the ink containing the notified polymer will be largely bound to the substrate to which it is applied.

Overall, the OHS risk presented by the notified polymer is not considered to be unacceptable, based on the low exposure to workers and the assumed low hazard of the polymer.

Public Health Risk Assessment

The notified polymer will not be sold to the public except in the form of printed articles. There is high potential for dermal exposure to the printed materials such as magazines. However, the notified polymer will be largely bound to the substrate to which it is applied and dermal contact should be limited to the fingertips only and therefore the exposure is expected to be low. The risk to public health is not considered to be unacceptable due to the assumed low hazard of the notified polymer.

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

The majority of the notified polymer will be bound within the cured printing matrix, adhering to the paper product articles and it will share the fate of the articles into which it is incorporated. It is anticipated that approximately half of these articles will be disposed to landfill and the remainder will be recycled at the end of their useful lifetime. During the paper recycling process, the notified polymer will be detached from the fibre, incorporated into the sludge from this process and finally disposed to landfill.

The notified polymer is not considered readily degradable based on its structure. In landfill, it is not expected to leach based on its hydrophobic structure and will undergo slow biotic and abiotic degradation processes into water and oxides of carbon, nitrogen and sulphur.

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

- 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.

- 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 to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical 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 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 chemical 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 products 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.