

File No PLC/919

July 2010

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

FULL PUBLIC REPORT

Polymer in NeoCryl B-814

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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	4
7. ENVIRONMENTAL IMPLICATIONS	5
8. CONCLUSIONS AND RECOMMENDATIONS	5

FULL PUBLIC REPORT**Polymer in NeoCryl B-814****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Reschem Technologies Pty Ltd (ABN 90 315 656 219)
6/56 Kalang Road
Elanora Heights, NSW 2101

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, Residual Monomers/Impurities and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Water solubility and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NeoCryl B-814 (Contains > 98% notified polymer)

MOLECULAR WEIGHT (MW)

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

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

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:	Colourless solid.
Softening Point	135°C
Density	1160 kg/m ³ at 20°C
Water Solubility	Not determined. The notified polymer is mainly composed of hydrophobic subunits and is therefore not expected to be soluble in water.
Dissociation Constant	Not determined. The notified polymer is expected to be ionised at environmental pH (4-9).
Particle Size	Surface weighted mean = 257 µm Volume weighted mean = 279 µm < 100 µm = 0%
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use, the polymer starts to degrade at temperatures above 250°C

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	< 5	< 10	< 10	< 15	< 15

Use

The notified polymer will be used as a component of flexographic printing inks and varnishes at concentrations up to 20% on a variety of plastic films. The notified polymer will only be used by industry, and reformulation and repackaging of the imported neat notified polymer is expected to be conducted via semi-automated processes.

Mode of Introduction and Disposal

The notified polymer will not be manufactured within Australia.

The notified polymer will be imported as a neat material (concentration > 98%) in 25 kg bags.

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 to the notified polymer (at > 98%) is possible during reformulation and packaging and when using the flexographic printing inks and varnishes containing the notified polymer (≤ 20%). Appropriate Personal Protective Equipment (PPE) including impervious gloves, safety glasses and coveralls to minimise dermal and ocular exposure is expected to be used by workers along with good hygiene practices. Inhalation exposure to the notified polymer is expected to be negligible based on the expected low vapour pressure (molecular weight > 10,000 Da) and the absence of particles of inhalable size (< 100 µm) in the imported bulk material.

Although exposure to the notified polymer could occur during reformulation, repackaging and end use, the risk to workers is not considered unacceptable due to its assumed low hazard.

Public Health Risk Assessment

The finished flexographic printing inks and varnishes containing the notified polymer are intended for industrial use only. However, there is potential for exposure to the public through dermal contact with surfaces that have been printed with flexographic printing inks and varnishes. Given that the notified polymer will be bound to the substrate on which it is printed and the assumed low hazard of the notified polymer, the risk to public health is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers 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. This does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

Environmental Risk Assessment

The notified polymer will be imported into Australia as a raw material and will be blended with other ingredients in a closed semi-automated system to form a finished ink. Approximately 1% of the notified polymer is expected to be spilt during reformulation and this is expected to be contained by bunding and disposed according to State/Territory regulations. Residual ink will be washed from equipment using recycled solvent and the washings will undergo a process of flocculation where the notified polymer will be removed and disposed of to landfill. The vast majority of the notified polymer will be bound within the cured printing matrix adhering to plastic film and the articles containing the notified polymer will ultimately be disposed to landfill. In landfill the notified polymer is expected to be immobile due to its very low solubility in water and since it is not expected to be readily degradable, based on its structure, it will undergo slow biotic and abiotic degradation processes into water and oxides of carbon. The notified polymer is not expected to cross biological membranes due to its high molecular weight and very low water solubility and is therefore not expected to bioaccumulate. The notified polymer is therefore not expected to pose a risk to the environment based on the reported use pattern.

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 expected 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 inks and varnishes, 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 the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.