

File No PLC/870

December 2009

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

FULL PUBLIC REPORT

Priplast 3192

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	6

FULL PUBLIC REPORT**Priplast 3192****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Croda Singapore Pty Ltd (ABN 34 088 345 457)
Ground Floor, Suite A1, 44-46 Mandarin Street
Villawood, NSW 2163

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, Import Volume and Identity of Analogues.

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

US, China and Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Priplast 3192

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 1,000 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:	Pale yellow waxy solid
Melting Point/Glass Transition Temp	Approximately 45°C
Density	1020 kg/m ³
Water Solubility	Claimed to be insoluble in water, which is consistent with the largely hydrophobic structure.
Particle Size	Waxy solid
Reactivity	Stable under normal environmental conditions. While the notified polymer contains hydrolysable functionality, this is not expected to occur within the environmental pH range of 4-9.
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	1-3	10-30	30-100	100-300	100-300

Use

The notified polymer will be used as a raw material in the production of polyurethanes. The polyurethanes will be used for solid elastomers and foams (30%), coatings (50%) and adhesives (20%).

The notified polymer will not be manufactured within Australia.

Production of solid elastomers and polyurethane foams will involve the notified polymer (< 60% concentration) being reformulated in a closed blending vessel with other additives to a resin premix (< 20% notified polymer). This mixture is then pumped out of the blending vessel to a high-pressure mechanical impingement mix head and mixed with further components to form the polyurethane and either aerated to produce foam (< 10% of the total amount) or added to moulds to produce solid elastomers. The polyurethane products are expected to contain < 2% notified polymer.

During the production of the adhesives the notified polymer will be reformulated in a closed mixing vessel under local exhaust ventilation before being dispensed into cartridges (typically less than 1 L). The final concentration of the notified polymer in the finished adhesive product will be generally less than 10%. Approximately 70% of the manufactured adhesive will be used in industry applications such as construction, woodworking, packaging, footwear, and the assembly of transport vehicles. With the remaining 30% sold to the public.

During the production of coatings the notified polymer will be reformulated in a closed mixing vessel under local exhaust ventilation before being dispensed into containers. The final concentration of the notified polymer in the finished coating product is generally less than 2%. The majority (90%) of the coating products, containing the notified polymer will be sold to commercial applicators with the remainder purchased by the public for DIY application. The coating products will be applied by roller (75%), brush (10%) or spray (15%).

Mode of Introduction and Disposal

The notified polymer will be imported in 200 L drums either as a 60% w/w formulation or as a 20% w/w water borne polyurethane formulation.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on analogous polymers.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
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Rat, acute oral	LD50 > 5,000 mg/kg bw	no	EC Directive 84/449/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Rat, acute oral	LD50 > 2,000 mg/kg bw	no	Analogue A OECD TG 401
Genotoxicity - bacterial reverse mutation	non mutagenic	no	Analogue B OECD TG 471
Genotoxicity - bacterial reverse mutation	non mutagenic	no	Analogue C OECD TG 471
			Analogue D

All results were indicative of low hazard.

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure to the notified polymer is possible from drips, spills and splashes during reformulation. The use of a closed mixing system and local exhaust ventilation is expected to reduce exposure. Appropriate Personal Protective Equipment (PPE) including impervious gloves, safety glasses and coveralls to minimise dermal and ocular exposure is also expected to be used by workers.

Dermal exposure to solid elastomers and polyurethane foams containing the notified polymer (< 2%) is expected by workers. However it will be incorporated into a polymer matrix and hence not bioavailable.

During spray application of coatings containing the notified polymer, dermal, ocular and inhalation exposure is possible. However the low concentrations (< 2%) and the expected use of PPE such as impervious gloves, safety glasses and coveralls should minimise exposure.

After applied coatings and adhesives containing the notified polymer have dried, it will be incorporated into a polymer matrix and hence not bioavailable.

Although exposure to the notified polymer could occur during reformulation processes, application of coatings and adhesives and handling of solid elastomers and polyurethane foams containing the notified polymer, the risk to workers is not considered unacceptable due to its assumed low hazard.

Public Health Risk Assessment

The public will only have contact with the reformulated products where the concentration will be low (< 10% for adhesives and < 2% for surface coatings). Dermal, ocular and inhalation exposure to these products is possible, however due to the assumed low hazard the risk to the public is not considered to be unacceptable.

There is potential for dermal exposure by the public to solid elastomers and polyurethane foams and dried coatings and adhesives that contain the notified polymer. The notified polymer will be incorporated into a polymer matrix and hence not bioavailable. Given exposure is expected to be negligible the risk to public health is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on analogue polymers.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	
Fish Toxicity	LC50 >1000 mg/L	no	OECD TG 203 Analogue B

All results were indicative of low hazard.

Environmental Risk Assessment

Aqueous waste streams from reformulation and use are expected to be treated on-site, with flocculated waste consigned to landfill and or be incinerated where regulations and facilities permit. These practices, together with the very low water solubility of the notified polymer, will ensure minimal aquatic exposure. All end-use forms of the notified polymer are expected to be eventually disposed of to landfill at the end of their useful life.

The notified polymer based on an analogous polymer (Analogue B) is not expected to be readily biodegradable. In landfill, the notified polymer is expected to be immobile and eventually degrade via biotic and abiotic process to form simple organic compounds. If incinerated, the notified polymer is expected to thermally degrade to water vapour and various oxides of carbon. It is a high molecular weight polymer with very low water solubility, and hence is not expected to cross any biological membrane and is unlikely to bioaccumulate. Therefore, the notified polymer is not considered to pose a risk to the environment.

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.

- Spray application should be carried out in accordance with the Safe Work Australia National Guidance Material for Spray Painting [NOHSC (1999)].
- 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 raw material in the production of polyurethanes, 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.