

File No PLC/812

March 2009

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

FULL PUBLIC REPORT

Priolube 2087

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**Priolube 2087****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Croda Singapore Pty Ltd trading as Croda Australia 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, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Import Volume.

NOTIFICATION IN OTHER COUNTRIES

USA (1991)

Korea (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Priobule 2087

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000 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:	Yellow liquid
Pour Point Temp	< -35°C
Boiling Point	> 200°C
Density	920 kg/m ³ at 20°C
Water Solubility	< 0.1 mg/L at 20°C. Estimated by EPIWIN which is consistent with the highly hydrophobic structural formula of the notified polymer.
Dissociation Constant	Not determined. However, the polymer contains terminal dissociable groups that typically have a pKa in the range of 3-5.
Reactivity	Stable under anticipated use conditions. The notified polymer contains unreacted functional groups of low concern which are not expected to react under the intended conditions of use.
Degradation Products	None under normal conditions of use. Hydrolysis is unlikely to occur throughout the environmental pH range of 4-9, despite the existence of hydrolysable functional groups in the polymer.

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	30-100	30-100	30-100	30-100	30-100

Use

The notified polymer will be used as an additive in synthetic lubricants at < 30%.

Mode of Introduction and Disposal

The notified polymer will be imported by sea in 200 L drums, iso-containers or bulk liquid containers for reformulation into lubricant products or as a component (< 30%) of a finished product.

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 the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 423
2. Genotoxicity - bacterial reverse mutation	non mutagenic	yes	OECD TG 471

Mutagenicity

The notified polymer was tested in a bacterial reverse mutation assay (Ames test), conducted both with and without metabolic activation at concentrations up to 5000 µg/plate according to OECD TG 471. Statistically significant increases in revertant colony frequency were observed in the TA1537 with metabolic activation at 50 and 500 µg/plate. However, the increases were only observed in 1 of 2 experiments, they were less than 1.4 times the concurrent solvent control and within the historical range for the strain, therefore the increase was not considered to be of toxicological significance. The notified polymer was considered to be non-mutagenic under the conditions of the test.

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure to the notified polymer (> 80%) may occur during processes such as transferring the notified polymer to the blending vessel, quality testing, filling product containers and cleaning of equipment during reformulation. However, engineering controls such as a closed, automated blending system and exhaust ventilation, and personal protective equipment (PPE) such as impervious gloves, safety glasses and protective clothing worn by workers are expected to minimise exposure.

There is potential for dermal and ocular exposure to workers during manual filling and draining of industrial

machinery and vehicles with lubricant products containing the notified polymer (< 30%). Exposure of the hands is the most likely, and may be minimised by wearing gloves. Safety glasses and overalls would also assist to minimise exposure.

Given the notified polymer has a low vapour pressure, inhalation exposure is not anticipated.

The notified polymer meets the PLC criteria and is therefore assumed to be of low toxicity. This is supported by the results in tests for the toxicological endpoints: mutagenicity and acute oral toxicity. Overall, based on the anticipated low exposure to workers and the expected low intrinsic hazard of the notified polymer, the risk to workers is not considered unacceptable.

Public Health Risk Assessment

The notified polymer is intended only for use in industry and as such public exposure to the notified polymer is not expected. As there will be no exposure of the public to products containing the notified polymer, the risk to the public from exposure to the notified polymer is not considered unacceptable.

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

No significant release of the notified polymer to the aquatic environment is expected.

The notified polymer is not considered readily biodegradable based on the provided test report, however, 62.9% biodegradation was observed after 28 days, indicating that the polymer will undergo slow degradation in landfill forming small molecules of water and oxides of carbon. The notified polymer has a high molecular weight and is insoluble in water. Based on these properties, the notified polymer is not expected to cross biological membranes, hence, it is unlikely to bioaccumulate.

Based on the reported use pattern and the physical properties of the notified polymer, it is not expected to pose an unacceptable risk to the aquatic ecosystem.

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 or incinerate to make use of the calorific content.

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 an additive used in lubricant products, 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.