

File No PLC/929

September 2010

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

**FULL PUBLIC REPORT**

**Hypermer A70**

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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****Hypermer A70****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Croda Singapore Pty Ltd Trading as Croda Australia (ABN 34 088 345 457)  
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, Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and Use Details.

## 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

China, Korea, Canada, US and EU

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Hypermer A70 (notified polymer).

## 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:	Dark brown viscous liquid
Melting Point/Glass Transition Temp	>21°C (pour point)
Density	0.97 kg/m <sup>3</sup> at 40°C
Water Solubility	Not determined. The notified polymer forms emulsions in water.
Dissociation Constant	Not determined. The notified polymer does not contain any dissociable functions at environmental pH (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	1-3	10-30	10-30	10-30	10-30

##### Use

The notified polymer will be used as a functional additive at <3% in lubricant fluids for the automotive, manufacturing and construction industry.

##### Mode of Introduction

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of industrial lubricant and hydraulic fluid formulation at <3% concentration in 200L steel drums and warehoused prior to transport to commercial and industrial customers.

#### 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>	
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	Not stated
2. Rat, acute dermal	LD50 >2000 mg/kg bw	no	Not stated
4. Rabbit, skin irritation*	mildly irritating	yes	Not stated
5. Rabbit, eye irritation*	mildly irritating	yes	Not stated
6. Skin sensitisation - adjuvant test	no evidence of sensitisation	no	Maximisation test
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471 – 472

\* Conducted with 10% of test substance in mineral oil (test substance contained notified polymer at >95% in xylene).

However, there is some concern relating to skin and eye irritation. No skin and eye irritation studies were performed with the neat notified polymer. A 10% preparation of notified polymer in mineral oil indicated a slight irritation to rabbit skin and eyes. This preparation of notified polymer also contained 0.5% xylene, which is irritating to skin. It is possible that slight skin and eyes irritation observed was due to xylene rather than the notified polymer.

The notified polymer can therefore be considered to be of low hazard and meet the PLC criteria.

#### Occupational Health and Safety Risk Assessment

The notified polymer will not be manufactured or reformulated in Australia. It will be imported at <3% in finished lubricants packaged in 200L steel drums for industrial use.

End users may be exposed via dermal or ocular route to the notified polymer at a concentration <3% during charging, topping up and maintenance activities as a result from drips, spills and splashes. Exposure will be minimised by the secure containment of the lubricant formulation and the use of PPE such as gloves, safety eyewear and overalls when handling lubricants containing the notified polymer.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the low concentration (<3%) of the notified polymer in the finished lubricant, minimal exposure to workers and low intrinsic hazard of the notified polymer.

### **Public Health Risk Assessment**

The product containing the notified polymer is intended only for use in industrial situations and as such, public exposure to the notified polymer is not expected.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

#### **7.1.1 Environmental Exposure**

##### **RELEASE OF CHEMICAL AT SITE**

The notified polymer will be manufactured overseas and will be imported as a component of finished lubricating products for the automotive, manufacturing and construction industries. No significant release is expected from the transportation and storage of the products containing the notified polymer.

##### **RELEASE OF CHEMICAL FROM USE**

The lubricating fluid containing the notified polymer will be used in sealed units, which may be topped up and refilled as required. The lubricating fluids are only available for industrial applications and as such the changing and topping up of the fluids will be conducted by trained tradespersons. No significant release of the notified polymer is expected from the removal of used lubricating fluid. During the use of lubricating fluid in sealed units, the notified polymer will be contained and its release is expected to be very low. The changed lubricating fluids are expected to be collected and stored for subsequent disposal. The release of the notified polymer from professional activities is expected to be limited by the requirements for appropriate disposal of waste oil according to State/Territory regulations.

In the manufacturing industry, lubricating fluid containing the notified polymer may be used for the cooling and lubrication of machine tools. Up to 25% of the total import volume of notified polymer will be used for this purpose. Such fluids are generally used in semi-enclosed circulatory systems. It is expected that the lubricating fluids will be disposed of via licensed waste disposal contractors. It is estimated that up to 50% of the lubricating fluid used in this application may be released directly to sewer, storm water drains or be placed in landfill.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

When lubricants containing the notified polymer are disposed of in accordance with State/Territory regulations, the notified polymer is expected to be recycled, re-refined or used as low grade burner fuel. It is likely that the notified polymer will be degraded into simpler compounds during re-refining with any residue partitioning to the heavy fractions such as lubricating oils or asphalt. If combusted, the notified polymer is likely to form oxides of carbon and water vapour. Similarly, during metal recycling of automotive components, the notified polymer will be completely combusted.

The lubricating fluid containing the notified polymer is expected to be collected at the end of the lifecycle of the sealed units and in the event of changing the fluid. As the notified polymer is for industrial use only, it is expected that the fluid will be collected and disposed according to State/Territory regulations.

#### **7.1.2 Environmental fate**

A study submitted by the notifier indicates the notified polymer is not readily biodegradable. The notified polymer is not expected to be bioaccumulative or bioavailable to aquatic organisms due to its high molecular

weight and expected low water solubility. Most of the notified polymer will be either thermally decomposed during use, recycling or refinement. A small amount of the notified polymer is expected to be sent to landfill as residues in containers or as a component of waste oil. The notified polymer is expected to be degraded into water and oxides of carbon by thermal decomposition in industrial facilities or by natural processes in landfill.

#### Study Summary: Ready Biodegradability

The environmental fate study was conducted according to OECD TG 301 B Ready Biodegradability: CO<sub>2</sub> Evolution Test. The percentage biodegradation of the test substance was expressed as a ratio of evolved carbon dioxide to the initial theoretical carbon added as test substance. All the validation criteria for the test were satisfied and the test substance reached a degradation of 18.5% by day 28 of the test indicating it is not readily biodegradable.

### **7.1.3 Predicted Environmental Concentration (PEC)**

The main release of the notified polymer to surface waters is expected to originate from the improper disposal of lubricants in the manufacturing industry, containing the notified polymer, to the sewer. It is estimated that up to 25% of the notified polymer will be used in the manufacturing industry and, assuming a worst-case scenario, up to 50% used for this purpose will be disposed of to the sewer. A worst case PEC for discharge of the notified polymer to surface waters has therefore been calculated assuming that 12.5% of the total imported quantity of the polymer will be discharged to sewers nation wide, 260 days per year and that no removal will occur in sewage treatment. The results of this calculation are a PEC<sub>river</sub> 3.41 µg/L and PEC<sub>ocean</sub> 0.34 µg/L. These are upper limits for the river and ocean PECs since there will be further mitigation of the notified polymer concentration in STPs due to adsorption of the polymer to sediment and sludge.

### **7.2. Environmental effects assessment**

The results from ecotoxicological investigations conducted on the notified polymer in xylene are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LL50 (96 h) > 100 mg/L	Not harmful to fish
Daphnia Toxicity	EL50 (48 h) > 100 mg/L	Not harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is not harmful to fish or aquatic invertebrates up to the limit of its solubility in water. Additionally, although the notified polymer is not readily biodegradable, it is not expected to bioaccumulate. The notified polymer is therefore not classified for acute or long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

#### Study Summary: Fish Toxicity

The ecotoxicological study was done according to OECD TG 203 Fish, Acute Toxicity Test. A static limit test was conducted following a range finding test. All validity criteria for the test were satisfied except that the concentration of the test substance was not monitored to ensure it was maintained over the test duration. However, it was reported that at the start of the test the test solution appeared to be a hazy dispersion with a slight foam on the test medium surface and remained so for the exposure period. The test did not fulfil all of the validity criteria but is deemed reliable. The test substance is not harmful to fish up to the limit of its solubility in water.

#### Study Summary: Aquatic Vertebrate Toxicity

The ecotoxicological study was done according to OECD TG 202 *Daphnia* sp. Acute Immobilisation Test. A limit test was conducted. All validity criteria for the test were satisfied. The concentration of the test substance was not monitored to ensure it was maintained over the test duration. However, it was reported that at the start of the test the test solution appeared to be a very pale white hazy dispersion and remained so for the exposure period. The test is deemed reliable. No immobility of daphnia was observed over the course of the test. The test substance is not harmful to daphnia up to the limit of its solubility in water.

### **7.2.1 Predicted No-Effect Concentration**

The predicted no-effect concentration (PNEC) was calculated with the toxicity endpoint for fish (> 100 mg/L) and an assessment factor of 1000, as the endpoints for only two trophic levels are available.

<b><i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i></b>		
LL50 (fish)	>100	mg/L
Assessment Factor	1000	
PNEC:	>100	µg/L

### 7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

<b><i>Risk Assessment</i></b>	<b><i>PEC µg/L</i></b>	<b><i>PNEC µg/L</i></b>	<b><i>Q</i></b>
Q - River:	3.41	> 100	0.034
Q - Ocean:	0.34	> 100	0.003

The concentration of the notified polymer in surface waters is expected to be very low based on the reported use pattern and the maximum import volume. It is not expected to bioaccumulate, based on its molecular weight and expected low water solubility. As the risk quotients are well below 1, the notified polymer is not expected to pose a risk to the aquatic 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 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 or accidental release of the notified chemical 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 functional additive in lubricant fluids for the automotive, manufacturing and construction industry, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased from 30 tonnes, 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.