File No PLC/1418

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in DE11110-LQ-(MV)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment and Energy.

This Public Report is 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

June 2017

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1418	Croda Singapore Pte Ltd (trading as Croda Australia)	Polymer in DE11110-LQ-(MV)	No	≤ 30 tonnes per annum	Additive for engine oil

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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 SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency Procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 additive for engine oil, 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 notified polymer 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.

Safety Data Sheet

The SDS of the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Croda Singapore Pte Ltd, trading as Croda Australia (ABN: 34 088 345 457)
Suite 102, Level 1, 447 Victoria Street
WETHERILL PARK NSW 2164

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 and residual monomers/impurities.

2. IDENTITY OF POLYMER

Marketing Name(s)
DE11110-LQ-(MV) (containing the notified polymer at ≤ 10%)

3. PLC CRITERIA JUSTIFICATION

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

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Dark orange odourless viscous liquid*
Melting Point/Glass Transition Temp	> 21 °C (pour point)
Density	970 kg/m^3 at 40 °C
Water Solubility	Not determined. The notified polymer may form emulsions in water.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*For DE11110-LQ-(MV) (containing the notified polymer at ≤ 10%)

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30	30	30	30	30

Use
The notified polymer will be used as a part of a lubrication additive for engine oil.

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of an additive package (containing the notified polymer at < 10%) and in formulated oils (containing the notified polymer at < 1%).

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by studies submitted on an analogue polymer for the following toxicological endpoints:

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 > 2000 mg/kg bw	no	Not stated
Rat, acute dermal	LD50 > 2000 mg/kg bw	no	Not stated
Rabbit, skin irritation*	mildly irritating	yes	Not stated
Rabbit, eye irritation*	mildly irritating	yes	Not stated
Skin sensitisation - adjuvant test	no evidence of sensitisation	no	Maximisation test
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471 – 472

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

Slight skin and eye irritation effects were noted in the abovementioned studies. No skin and eye irritation studies were performed with the neat analogue polymer. A 10% preparation of the analogue polymer in mineral oil indicated slight irritation to rabbit skin and eyes. This preparation of analogue polymer also contained 0.5% xylene, which is irritating to skin. It is possible that the slight skin and eye irritation observed was due to xylene rather than the analogue polymer.

Overall, the notified polymer is considered to be of low hazard. Therefore, the risk of the notified polymer to occupational and public health is not considered to be unreasonable given the low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment. The notified polymer will be imported as a component of additive packages for engine oil or as a component of finished oils. No significant release of the notified polymer is expected from transportation and storage. Local blending and repackaging of the additive containing the notified polymer into lubricants is expected to occur within enclosed automated systems. During the blending processes, approximately 1% of the notified polymer is estimated to be released to the environment as accidental spillage. Accidental spills and leaks will be contained and collected for recycling where appropriate, or disposed of in accordance with local government regulations, most likely to landfill.

The majority of the notified polymer used in automotive oils is expected to be used within closed systems, and be consumed and thermally decomposed during its use. The major release of the notified polymer may come from inappropriate disposal of used oils. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that around 86% of oil changes take place in specialised automotive service centres where old oil is disposed of responsibly (e.g. oil recycling), and negligible release of the notified polymer is expected. The remaining 14% of oil is used by DIY consumers. According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997), approximately 20% of oil

used by DIY consumers is collected for recycling, approximately 25% is buried or disposed of to landfill, 5% is disposed of into stormwater drains, and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. Under the worst case scenario, the percentage of the imported quantity of notified polymer inappropriately disposed to stormwater drains is estimated to be 0.7%. That is, 14% (fraction collected by DIY users) × 5% (fraction disposed to stormwater). The release of the notified polymer may be up to 210 kg/year (= 30 tonnes/year × 0.7%). In this worst case scenario, it is assumed that the release goes into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 210 kg and the annual volume of water drained from this region estimated to be 250 × 10^6 m^3, the calculated PEC will be up to 0.84 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple regions and it will be further diluted before it reaches the ocean.

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 has potential to be readily biodegradable based on its functional groups. Based on its high molecular weight and expected low water solubility, the notified polymer is not expected to cross biological membranes, and expected to have low potential to bioaccumulate. The notified polymer is expected to be degraded into water and oxides of carbon by thermal decomposition in industrial facilities or via biotic and abiotic processes in landfill. Therefore, based on its low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

AIP (1995) AIP Survey of used oil. Australian Institute of Petroleum Ltd.

Snow R (1997) Used oil management. Paper presented at the Used Oil Management Conference, Brisbane, August 1997, Queensland Department of the Environment.