File No PLC/1182

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in IDN 6965A

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

January 2013

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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/1182	IMCD Australia Ltd	Polymer in IDN 6965A	No	≤ 200 tonnes per annum	Component of lubricant or fuel additives

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the 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 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.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)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 for the 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.

Disposal

- The notified polymer should be disposed of in accordance with local regulations for recycling, re-use or recovery.

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 a component of lubricant or fuel additives, 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.

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
IMCD Australia Ltd (ABN 44 000 005 578)
1st Floor, 372 Wellington Road,
Mulgrave, VIC 3170

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 and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
IDN 6965A

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da

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	Pale brown solid
Glass Transition Temp	16 – 25 °C*
Density	0.934g/cm^3 at 15.6 °C
Water Solubility	< 0.0001g/L at 20 °C (as per OECD Guideline 105)*
Flash point	170 °C
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*Data from an analogue of the notified polymer

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 200	< 200	< 200	< 200	< 200

Use
The notified polymer will not be manufactured within Australia, but will be imported into Australia at a concentration of < 50% in a lubricant additive for reformulation or at concentrations of < 10% in finished lubricants. The notified polymer will be used as an additive in lubricating oil at < 10% concentration, predominately for industrial applications.

6. HUMAN HEALTH RISK ASSESSMENT

The results from toxicological investigations conducted on the notified polymer and an Analogue are summarised in the table below.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 >5000 mg/kg bw*	no	OECD TG 423
2. Rat, repeat dose oral gavage toxicity – 28 days.	NOEL ≥1000mg/kg bw/day	no	OECD TG 407
3. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471 Pre-incubation procedure.
4. Genotoxicity – in vitro Mammalian chromosome aberration	non genotoxic	no	OECD TG 473

*Study performed on an analogue of the notified polymer

Published data/information on a structurally similar analogue of the notified chemical is available (the identity of the analogue chemical and information sources are considered exempt information).

All results were indicative of low hazard.
The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard, the negative results observed in the genotoxicity tests and the assessed use pattern.

Acute toxicity.
The oral LD50 of an analogue of the notified polymer was found to be greater than 5000 mg/kg bw/day.

Repeated dose toxicity.
A 28 day repeat dose study by oral gavage for the notified polymer was conducted in rats. Analysis of clinical appearance, functional observations, body weight, food and water consumption did not reveal any toxicologically significant abnormalities between the treated and the control groups up to 1000 mg/kg bw/day. The No Observed Effect Level (NOEL) for systemic toxicity was established by the study authors as 1000 mg/kg bw/day based on the absence of effects at any dose.

Mutagenicity/Genotoxicity.
The notified polymer was shown not to be mutagenic in a bacterial reverse mutation study (in the presence or absence of metabolic activation) and was not clastogenic in an in vitro mammalian chromosome aberration test on human peripheral blood lymphocytes.

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

Polymers without significant ionic functionality are generally of low concern to the environment. This is supported by environmental endpoints observed in tests conducted on the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 (96 h) > 100 mg/L	Not Harmful
Daphnia Toxicity	EL50 (48 h) > 100 mg/L	Not Harmful
Algal Toxicity	IL50 (72 h) > 100 mg/L	Not Harmful

All results are indicative of low hazard for the notified polymer. The notified polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility and is therefore not expected to bioaccumulate. The notified chemical is not readily biodegradable.

The notified polymer will be manufactured overseas and will be imported as a component of an additive in lubricating oil at < 10% concentration, predominately for industrial applications. No significant release is expected from the transportation and storage of the products containing the notified polymer. If incidental spillage of the additive package occurs during normal blending procedures, it will be contained and soaked up with earth or sand before being transported off-site to an approved industrial facility for appropriate disposal.

The lubricating fluid containing the notified polymer will be used in sealed units, which may be topped up and refilled as required. 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 industrial activities is expected to be limited by the requirements for appropriate disposal of waste oil according to State/Territory regulations.

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 which will be used as lubricating oils or asphalt. During combustion, the notified polymer is expected to form oxides of carbon and water vapour.

The notified polymer is not expected to be released to the aquatic compartment in ecotoxicologically significant concentrations. Therefore, on the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.