File No PLC/792

August 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Irgaflo 710P

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba (Australia) Pty Ltd (ABN 97 005 061 469)
235 Settlement Road
THOMASTOWN VIC 3074

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, Manufacture/Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24A OF THE ACT)
No variation to the schedule of data requirements is claimed.

NOTIFICATION IN OTHER COUNTRIES
Europe, Korea, USA, Canada, Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irgaflo 710P

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000 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.

The notified polymer contains only low concern functional groups.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Viscous white to off-white translucent liquid
Melting Point	-12°C to 5°C
Density	931 kg/m^3 at 25°C
Water Solubility	<1.14x10^{-3} g/L at 20°C (GPC analysis)
Dissociation Constant	The polymer does not contain any acidic or basic groups
Reactivity	Stable under normal environmental conditions

Degradation Products	None under normal conditions of use
Hydrolysis	The notified polymer contains ester functionalities which have the potential to hydrolyse. However, given the low water solubility of the polymer this would be unlikely in the environmental pH range of 4-9.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

USE

The notified polymer will be used at ≤0.2% in lubricant products, such as transmission fluids, hydraulic and gear lubricants.

Mode of Introduction and Disposal

The notified polymer will be imported by sea or air at 40% in oil formulations for use in lubricant products.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard.

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure to the notified polymer (<40%) may potentially occur during processes such as connection and disconnection of hoses to blending vessels and filling product containers during reformulation. However, engineering controls and personal protective equipment (PPE) worn by workers are expected to minimise exposure.

The potential for dermal and ocular exposure also exists during the draining and filling of lubricant products containing the notified polymer (≤0.2%) in mechanical workshops. Exposure of the hands is the most likely, and may be minimised by wearing gloves.

Workers may experience accidental and dermal exposure to the notified polymer at up to 40% during reformulation. However, the polymer is assumed to be of low hazard, therefore this exposure is not expected to be unacceptable.

Public Health Risk Assessment

Do-it-yourself (DIY) users may experience dermal and ocular exposure to the notified polymer at ≤0.2% in lubricant products similar to that described above for use in mechanical workshops when adding lubricant products to automobiles and other machinery. However, DIY users are expected to use lubricant products less frequently than workers in mechanical workshops and therefore exposure is expected to be less frequent. The overall risk to public health is not expected to be unacceptable given the assumed low hazard of the notified polymer and the infrequent use of products containing the notified polymer by consumers.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. The notified polymer is non-ionic and stable under normal environmental conditions and therefore is not expected to be a concern to aquatic life.

Environmental Risk Assessment

Lubricant use will be mainly to sealed units and hence limited release to the environment is expected, mainly on disposal and from formulations losses. Disposal by professionals is expected to result in very little being improperly discarded to aquatic compartment. Therefore, the risk presented by the proposed use is not expected to be unacceptable.

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, though it may be incinerated.

Emergency procedures

- Contain the spilled material with suitable absorbent material. Scoop into marked containers for disposal as chemical waste.

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 additive in lubricant products, or is likely to change significantly;

- the amount of notified polymer being introduced has increased from 30 tonnes, or is likely to increase, significantly;
- if 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of product containing 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.