

File No EX/136 (PLC/744)

May 2010

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

FULL PUBLIC REPORT

Polymer in IRGAFLO 649 P

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 and Water Resources.

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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FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Polymer in IRGAFLO 649 P. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

Polymer in IRGAFLO 649 P**1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Ciba (Australia) Pty Limited (ABN 97 005 061 469)
235 Settlement Road
Thomastown VIC 3074

and

Mobil Oil Australia Pty Ltd (ABN 88 004 052 984)
12 Riverside Quay
Southbank Vic 3006

Applicant for an Extension of the Original Assessment Certificate:

Lubes Direct Pty Ltd (ABN 72 117 841 308)
174 Coreen Avenue
Penrith NSW 2750

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, Import Volume, Details of Use

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)

No

NOTIFICATION IN OTHER COUNTRIES

Europe (EINECS), Korea (2007), USA (2006), Canada (2006), Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME

IRGAFLO 649 P (Product containing the notified polymer)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 10000 Da

Reactive Functional Groups

The notified polymer contains only low concern functional groups.

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 | Viscous, yellowish translucent liquid |
| Melting Point/Glass Transition Temp | -35°C to -16°C |
| Density | 928.8 kg/m ³ at 25°C |
| Water Solubility | < 9.92 mg/L* |
| | The solubility value is consistent with its hydrophobic structure. |
| Reactivity | Stable under normal environmental conditions |
| Degradation Products | None under normal conditions of use. While the notified polymer contains hydrolysable functionality, this is not expected to occur under standard environmental conditions (pH 4-9). |

*Measured by sonicating 2 g in 500 mL water for 30 minutes then warming to 60°C overnight while stirring. After cooling and filtration, the solubility was determined by GPC.

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 |
| <i>Extension Application</i> | | | | | |
| Year | 1 | 2 | 3 | 4 | 5 |
| Tonnes | 4 | 4 | 4 | 4 | 4 |

Use

Pour point depressant for use in industrial and automotive lubricants and transmission oil for industrial and mining machines.

The notified polymer is combined with other additives to form the final transmission fluid or lubricant. The blended products containing the notified polymer (up to 0.2%) are used in auto manufacturing plants to fill new car parts or in auto or machinery workshops if these oils/fluids require changing. Transfer may be manual or semi-automatic using pumping equipment.

Extension Application

The notified polymer will be imported in finished lubricant products at < 1% for use in the maintenance of industrial machinery.

Mode of Introduction and Disposal

The notified polymer will be imported by sea or air in 180 kg UN-approved closed head steel drums as a 40% solution in lubricating oils, for blending with other additives to form the final transmission fluid, hydraulic or gear lubricant. It will also be imported in finished transmission oil at < 1% w/w in 20 L and 208 L drums.

Extension Application

The notified polymer will be imported as a component of automotive lubricant products at < 1% in intermediate bulk containers (IBCs), 208 L drums, and containers of up to 20 L.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

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

Occupational Health and Safety Risk Assessment

Transport and storage

Transport and storage workers would only be exposed to the notified polymer at up to 40% in the event of a spill. The sealed containers used for transport minimise the likelihood of release or loss of the notified polymer in the case of an accident.

Comment [j1]: Exposure description should be incorporated in the risk assessment

Reformulation

Dermal and ocular exposure to the notified polymer may potentially occur during opening and closing of drums, connecting pipe lines for the blending operation and during mixing. However, exposure to significant amounts of the notified polymer is limited because of the semi-automated processes, and the personal protective equipment (protective aprons, gloves, boots, face shield) worn by workers.

End-use

Dermal and ocular exposure to the blended products containing the notified polymer (< 1%) may occur during the changing of automotive lubricants in automobile workshops, auto manufacturing plants or machinery workshops. Protective equipment may not be worn in these workplaces. Exposure to the notified polymer by workers at the end-use site is expected to be infrequent and minimal.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the low exposure to workers and the expected low intrinsic hazard of the polymer.

Public Health Risk Assessment

The public may be exposed occasionally to the blended products containing the notified polymer (< 1%) through operations such as changing gear oil, transmission fluid or hydraulic fluid. The route of exposure would be largely dermal, however some ocular exposure may also occur. However, the risk to public health will be negligible based on low hazard and low exposure.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of relatively low hazard. This is largely supported by environmental endpoints observed in testing conducted on the notified polymer (test reports not supplied).

| <i>Endpoint</i> | <i>Result</i> | <i>Effects Observed?</i> | <i>Test Guideline</i> |
|-------------------------|---|--------------------------|---|
| Fish Toxicity | LC ₅₀ : > 100 mg/L (WAF) ^{1,2} NOEC: 100 mg/L (WAF) | no | USEPA TG 850.1085 (1996) Static Test |
| Daphnia Toxicity (48 h) | IC ₅₀ : > 100 mg/L (WAF) ² NOEC: 100 mg/L (WAF) | no | OECD TG 202 (2004) Static Test |
| Algal Toxicity (96 h) | E _r C ₅₀ : 83 mg/L (WAF) NOE _r C: 25 mg/L (WAF) | yes | USEPA TG 850.5400 (1996) |

¹WAF = Water Accommodated Fraction

²Test conducted in the presence of humic acid (10 mg/L).

Brief details of the algal toxicity test indicate that there was no inhibition after 72 h in 6.3, 13, 25, 50 and 100 mg/L nominal WAF test concentrations. As there is no indication of the extent of notified polymer in the WAFs, it can only be concluded that there are some effects to algae below the level of water solubility.

Environmental Risk Assessment

Comment [j2]: Environmental Release and Fate to be incorporated in this section

The notified polymer will not be manufactured in Australia but is likely to be blended to form end use products, such as automatic transmission, and gear and hydraulic pump lubricants. The blending is performed in an automated or semi-automated enclosed system, with residual material in blending tanks and from cleaning of the equipment being recycled to the next batch to the extent practicable. Any spills are likewise expected to be re-used to the extent practicable. Minimal environmental exposure is expected from this route.

Disposal:

Each year, about 581 million litres of lubricating oil is sold in Australia, and about 303 million litres of waste oil is generated. The remainder is consumed during engine operation, unrecoverable or unaccounted for (Meinhardt 2002). The greatest potential for environmental release of the notified polymer is through disposal of oil product wastes. A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified polymer should result from these professional activities. The remaining 14% of oil (up to 4.2 tonnes of the estimated maximum 30 tonnes of notified polymer imported per annum) is removed by "do it yourself" (DIY) enthusiasts. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil.

According to a survey tracing the fate of used lubricating oil in Australia (Snow R 1997), only approximately 20% of used oil removed by DIY enthusiasts is collected for recycling, approximately 25% is buried or disposed of in 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. In a worst case scenario involving the 14% of used oil removed by DIY enthusiasts, the notified polymer could be collected for recycling (≤ 840 kg/y), buried or disposed of in landfill (≤ 1050 kg/y), disposed of in stormwater drains (≤ 210 kg/y) and used in treating fence posts, to kill weeds or disposed of in other ways (≤ 2100 kg/y). A proportion of the latter may potentially be disposed of to sewer. Therefore, about 0.7% (up to 210 kg/y) of the total import volume of the notified polymer could potentially enter the aquatic environment via disposal into the stormwater system. In addition to this, considering the unknown fate of some of the oil used by DIY operators, up to 7% (i.e. 50% of 14%; < 2100 kg/y) may also be sent to the sewer for disposal. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified polymer in neat concentrations is very unlikely except as a result of transport accidents. Any releases to water will adsorb strongly to sediment based on the very low water solubility.

Spent packaging material and container residues are disposed of to landfill or incinerated. Emptied drums are likely to be cleaned with mineral oil and reconditioned, with oily waste potentially containing 1% of the formulation reused in subsequent batches or concentrated and incinerated. Emptied drums may also be collected for metal recycling. Assuming ~1% of the imported formulation remains in emptied drums, an estimated maximum quantity of ≤ 300 kg/y will be generated as waste by this route based on a total annual import volume of < 30 t/y of the notified polymer.

Environmental fate:

If combusted the notified polymer is likely to form oxides of carbon and water vapour. Similarly during metal recycling of automotive components the polymer will be completely combusted.

Biodegradability:

A modified Sturm Test was performed according to OECD TG 301 B (1981). The mean cumulative CO₂ evolved from the aqueous medium fortified with XPDL 649 at 10 mg carbon/L was 19.4% of the theoretical amount. The result indicates that the test material is not readily biodegradable. As the notified polymer is poorly soluble in water, it is therefore expected to bind to soil in landfill and should eventually degrade by biotic and abiotic processes.

As release to the aquatic environment is minimal and diffuse, the risk to the aquatic environment is expected to be acceptable.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Risk assessment relating to Extension Application

The use and the fate of the notified polymer will not change under the proposed extension. The increase in proposed introduction volume is not expected to significantly change the environment and health impacts. Therefore, there are no changes required in the risk assessment

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 by incineration where appropriate.

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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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(2) of the Act; if
- the function or use of the chemical has changed from pour point depressant for use in industrial and automotive lubricants and transmission oil for industrial and mining machines, or is likely to change significantly;
 - the amount of chemical being introduced has increased to more than 30 tonnes per annum, or is likely to increase, significantly;
 - if the chemical 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.

Comment [s3]: Use for imported chemicals. Delete if the chemical is already manufactured in Australia

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 the notified chemical and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application:

The extension applicant has provided an MSDS for a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

References

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

Meinhardt (2002) Used oil in Australia. Prepared by Meinhardt Infrastructure & Environment Group for the Australian Government Department of the Environment and Heritage, Canberra.

Snow R (1997) Used Oil Management. Paper presented at the Used Oil Management Conference, Brisbane, August 1997, Queensland Dept. Environment.