File No PLC/798

22 July 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Infineum C9290

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)
Infineum Australia Pty Ltd (ABN 24 084 881 863)
Level 2, 6 Riverside Quay
Southbank VIC 3006

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, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details and Import Volume.

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)
SAPLC/65

NOTIFICATION IN OTHER COUNTRIES
Korea and the Phillipines

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Infineum C9290 (product containing the notified polymer)

CAS NUMBER
Not assigned

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >1000 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:	Homogeneous, dark amber to reddish brown solid, or very viscous liquid (Test guidelines: 830.6303) – tested on a 30-70% concentrate sample.
Melting Point/Glass Transition Temp	Not conducted as the notified polymer is only present in solution.
Density	925 kg/m^3 at 15°C (ASTM 1298) (tested on a 30-70% concentrate sample)
Water Solubility	< 0.167 × 10^{-3} g/L at 20°C (tested on a 30-70% concentrate sample), The solubility of the test substance was determined in HPLC-grade reagent water at 20°C using the shake flask method and analysed by high performance liquid chromatography. Based on the results of a shake flask solubility study, the solubility of the test substance in water at 20°C was determined to be less than Limit of Quantitation (LOQ) (0.167 mg/L).
Dissociation Constant	The dissociation constant cannot be measured or estimated, because of the lack of water solubility (a pre-requisite for the test).
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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1000-3000	3000-10,000	3000-10,000	3000-10,000	10,000-20,000

Use
The notified polymer functions as a lubricant additive component and is used together with other components to formulate engine oil. It is present at concentrations at < 10% in engine oil.

The notified polymer will not be manufactured in Australia. It is imported as Infineum C9290 or as part of a lubricant additive package at concentration ranging from 10-40% w/w. The imported products will be reformulated at the customer's site by blending with oils and other additives to form the completed lubricants. The reformulation will be a batch process, generally producing between 5000 and 50,000 L of finished lubricant. The blending will be mostly an automated process. For the additive package shipped in isotanks, the process will involve the operator attaching a flexible transfer hose to the container, the additive being pumped out and blended in an enclosed automated system, the hoses and pumps being flushed out with clean mineral oil, and the hose being disconnected. For shipments in drums, operators will open the drum, and either tilt (manually or with a mechanical device) into a pit containing the base oil and other additives which is then pumped away into a blending kettle, or, alternatively, the operator will introduce a spear into the drum and suck the product out directly into the blending kettle. The blended finished lubricant containing < 10% notified polymer is then repackaged into smaller containers or drums in volumes ranging from 1 to 1000 L and transported to end users.

Mode of Introduction and Disposal
The notified polymer will be imported as Infineum C9290 or part of an additive package to be used at customers' blending sites. It will be imported into Australia through the Melbourne and Brisbane ports in 205 L drums or bulk vessels such as iso-containers and bulk liquid containers (BLC).

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 at a 30–70% concentration.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 423
2. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

Occupational Health and Safety Risk Assessment
Dock workers and transport workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage. During reformulation dermal and ocular exposure may potentially occur during certain processes (e.g. drips and spillage during the transfer, blending and packaging processes, equipment cleaning and maintenance). However, exposure to significant amounts of the notified polymer is expected to be minimal because of the automated nature of most of the processes involved in reformulation, together with the engineering controls in place in the workplace and the personal protective equipment worn by workers.
A large number of motor mechanics may be exposed to products containing the notified chemical at concentrations of < 10% during the changing of engine oil. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. Exposure may be reduced by the use of PPE such as gloves, coveralls and safety glasses and good hygiene practices.

Although exposure to the notified polymer could occur during reformulation and end use by motor mechanics, the risk to workers is considered to be low due to the assumed low hazard of the notified polymer.

Public Health Risk Assessment
Products containing the notified polymer are primarily intended for use by industry and therefore public exposure to the notified polymer is expected to be low. However, exposure may occur during the changing of engine oil in automobiles by the public, although this will only be on an infrequent basis. Exposure will primarily be dermal although ocular exposure is also possible. PPE is not expected to be worn by the public. However, the risk to public health will be negligible because the notified polymer is of assumed low hazard.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

Environmental Release
Environmental release is expected to be minimal. Blending operations are performed at specially constructed sites and the notified polymer will be delivered to and stored at the blending facilities. No environmental release is expected during transport and storage operations, except through accidental spills or leaks of the drums or steel packaged containers. Small quantities may be released to the environment during the reformulation process, when the transfer of product from storage containers to the blending tanks occurs, during the connection and disconnection of transfer hoses. Any such spills and leaks would be contained within concrete bunds at the facility and soaked up with inert absorbent material and disposed of via the proper routes such as recycling and incineration.

Environmental release of the notified polymer in finished lubricants may also occur from end-use situations, although this is expected to be minimal. Lubricants, containing < 10% of the notified polymer could either be spilt or left as residues in containers as a result of transfer operations. Most spills are likely to be adsorbed onto sawdust and incinerated, while residues left in containers would be expected to be disposed of in a similar fashion and not released to the environment.

Environmental Fate
The notified polymer cannot be considered to be readily biodegradable under the strict terms and conditions of OECD Guideline 301C. It is a high molecular weight polymer with very low water solubility, and hence is not expected to cross any biological membrane and enter an organism's metabolic system and is unlikely to bioaccumulate.

7.2. Environmental Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by testing conducted on the notified polymer (a 30-70% concentrate sample).

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Daphnia Toxicity	EC50 > 100 mg/L	No	OECD TG 202

The result is indicative of low hazard.

7.3. Environmental Risk Assessment

The environmental hazard from the notified polymer is considered to be minimal. The polymer is a component of a lubricant for use primarily in industrial situations where proper disposal of material by incineration or recycling will be general practice.

Release of the notified polymer to the aquatic environment will be negligible except in cases of major spills, e.g. during transport. The low toxicity in acute daphnia study indicates a low aquatic toxicity potential. Due to its low water solubility, spills of notified polymer are expected to float on the surface, and migrate from water to the land; it is also expected to partition to sediment and wastewater solid. The high molecular weight and low water solubility will limit absorption of the molecule by all organisms. These physical characteristics will minimise the potential of the notified polymer to cross any biological membrane and enter an organism's metabolic system.

Incineration of the notified polymer would produce water vapour and oxides of carbon.

Overall, the notified polymer is not considered to pose a risk to the 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 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.

Environment

- The following control measures should be implemented by the customers' site to minimise environmental exposure during use of the notified polymer:
  - Bunding

Disposal

- The notified polymer should be disposed of by supervised incineration at very high temperatures to prevent formation of undesirable combustion products. Accidental leaks and spillage should be cleaned up promptly with absorbent material and put into containers for disposal. The empty drums and their residues should be disposed in accordance with government regulations.

Emergency procedures

- Spills/release of the notified polymer should be handled by recovery and/or confinement of spills where possible.
  - For small land spills, absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. If liquid is too viscous for pumping, shovel it up into a suitable container for recycle or disposal.
  - For water spills, confine spill immediately with booms. Warn other shipping. Remove from the surface by skimming or with suitable absorbent. Report spills as required to appropriate authorities.

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 lubricant component in engine oil at < 10% w/w, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased from 20,000 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.

Material Safety Data Sheet
The MSDS of the notified polymer 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.