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November 2008

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

FULL PUBLIC REPORT

Infineum C9535

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:

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**Director
NICNAS**

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Infineum C9535

This assessment report is for an extension of original assessment certificate for Infineum C9535. 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.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of the original assessment certificate (No.1905, PLC/492)

Infineum Australia Pty Ltd (ABN 24 084 881 863)

Level 2, 6 Riverside Quay

SOUTHBANK VIC, 3006.

Applicant for an extension of the original assessment certificate:

Shell Company of Australia Ltd (ABN 46 004 610 459)

8 Redfern Road

EAST HAWTHORN VIC 3123.

NOTIFICATION CATEGORY

Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Identity, Molecular Weight, and Polymer Constituents.

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)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2003): NSN Number 12378

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Notified polymer: Infineum C9535.

The notified polymer will be imported as part of a commercial diesel fuel additive with the Trade name Infineum R570.

Extension Applicant:

The notified polymer will be imported as a component of diesel fuel.

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes

No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>					
<i>Infineum</i>	100-200	100-200	100-200	100-200	100-200
<i>Shell</i>	< 200	< 200	< 200	< 200	< 200

USE

The notified polymer is a cold flow additive for use in diesel fuels. It improves the operability of diesel engines in cold weather by modifying the shape of the precipitating wax crystals in diesel fuel. The notified polymer is a gel at ambient temperature and as such it is distributed with additional solvents to improve its flow characteristics.

Extension applicant:

The notified polymer will be imported as a component of diesel fuels at < 200 ppm.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Import, transport and distribution

The notified polymer is imported as a component (approximately 77%) of the fuel additive Infineum R570 in both 205L drums and in bulk liquid containers. The fuel additive is transported by road to the customer storage facilities or refineries. It is anticipated that there will be six deliveries per year to seven refinery sites in Australia.

Fuel formulation

Typically, 1-4 workers are involved in the blending process per site. The fuel additive container is connected by the operator to the transfer system via a flexible transfer hose. Appropriate amounts of additive are then pumped out of the containers into the blend tank, where it is mixed with diesel fuel and other multi-purpose additives. On completion, the container, transfer hose/pipeline and pump are flushed through with diesel fuel. The transfer hose is then disconnected. At each site there is anticipated to be one batch (typically 10000-100000 litre) processed each week. The finished diesel fuel will typically contain approximately 200ppm of the new additive (144ppm notified polymer). The finished fuel is then automatically pumped out for distribution to customers around Australia by ship or road tanker for consumer use.

Other than the connection/disconnection of hoses, the process is fully automated. Workers will be provided with suitable protective clothing including gloves, safety glasses, overalls and safety shoes. Local exhaust ventilation would be employed at all sites where natural ventilation is considered inadequate.

End Use

At service stations, the diesel fuel will be transferred to underground tanks. When required the diesel fuel would be pumped directly into automobile fuel tanks.

Extension Applicant:

Diesel fuel containing the notified polymer (at < 200 ppm) will be imported in tanker ships and transported by road or rail to service stations. Addition of the fuel additive containing the notified polymer to the diesel fuel will occur overseas and will not be performed within Australia.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

No release of the notified polymer is expected at the customer sites during transport and blending, except in the event of an accidental spill. Any spills occurring during blending operations are to be contained and soaked up with earth or sand before being transported off-site to an approved facility for appropriate disposal. Release of the notified polymer to the atmosphere is unlikely to occur as the relative vapour pressure is expected to be low. Should any minimal leakage from product transfer operations occur, it would be collected and recycled or properly disposed of. Approximately 1% of the additive may remain in the import containers after emptying. This equates to less than 2 tonnes per year, assuming the maximum yearly import volume of 200 tonnes. The import containers and any residual product will be sent to a reconditioning facility, where they are to be cleaned and the residues are expected to be disposed of by incineration.

The end use of the additive will be as cold flow modifier in diesel fuel. No significant release of the notified polymer is expected at end use because the notifier expects the substance will be consumed in the automotive engine along with the diesel fuel to generate primarily carbon dioxide and water and thus disposal considerations will not be necessary.

There are expected to be minor spills at petrol stations, which would mostly fall to the ground. The fuel will evaporate with time leaving the residual polymer behind. The residual polymer is unlikely to undergo hydrolysis (due to low solubility in spite of the presence of hydrolysable groups) but will slowly degrade through the agency of abiotic and biotic process.

No data on the effect on diesel emissions were available. As the notified polymer contains no nitrogen, the NO_x formation that would occur during combustion with nitrogen in the air would depend on the amount of air and the peak combustion temperature. A typical treat rate would be 75 - 300 ppm of the notified polymer. Assuming 90% carbon atoms are converted to CO₂, the CO₂ levels would be in the range of 240-990 ppm (0.024-0.099%). If it all converted to hydrocarbons, the emission would be in the same ppm range. It is claimed the emission measuring techniques would not be able to detect that level of difference. The notifier claimed that if the combustion of the polymer was incomplete, then there should be increased levels of injector and combustion chamber deposits resulting in field complaints. This has not been the case in the several years that the notified polymer has been in use.

6.2. Summary of Occupational Exposure

Import, transport and distribution

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Fuel formulation

Dermal and ocular exposure can occur during certain formulation processes e.g. connection/disconnection of transfer hoses. However, exposure to significant amounts of the notified polymer is limited due to engineering controls and personal protective equipment worn by workers.

End Use

Exposure of transport drivers and service station personnel to drips and spills may occur during the connection and disconnection of transfer hoses and during automobile fuel fills. Exposure is expected to be negligible due to the closed systems used and the low concentration of notified polymer in the diesel fuel (144ppm).

6.3. Summary of Public Exposure

The notified polymer will be available to the public only after it has been mixed with diesel fuel at the refinery. Incidental exposure could occur during filling of the automobile fuel tank. Given the low concentration (144ppm) and the minimal direct contact with fuel under normal circumstances, public exposure is expected to be minimal.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Opaque to clear gel
Pour Point	12°C
Boiling Point Range	188.5 °C – 732.0 °C
Density	893.6 kg/m ³ at 15.56°C
Vapour pressure	Expected to be very low, <2.4 X 10 ⁻²⁹ kPa according to computer estimates based on the lowest molecular weight fragment.
Water Solubility	2.3x10 ⁻⁸ – 2.9x10 ⁻⁷ g/L at 20°C. These figures were estimated using a Log Kow of 4.6 as an input value (corresponding to approximately 72% of the components eluted via HPLC) and cover a range of molecular weights.
Partition Coefficient	The partition coefficient (Pow) of the test substance was estimated by reverse phase HPLC. The test substance was eluted as several component groups by HPLC. The estimated log Pow were 3.6, 4.2, 4.6 and 5.1 with one constituent at log Pow >6
Flash Point	88.9 °C (in imported product)
Explosive Properties	A negative result is predicted on structural grounds.
Reactivity	The notified polymer does not degrade or decompose at ambient temperatures. Hazardous polymerisation does not occur. However, contact with strong oxidising agents should be avoided.
Degradation Products	Oxides of Carbon.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were taken from the Health Canada NSN Health Assessment Summary for the notified polymer (NSN number 12378).

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral	low toxicity, oral LD50 >2000 mg/kg bw	no	yes
Rat, acute dermal	low toxicity, dermal LD50 >2000 mg/kg bw	no	no
Rat, oral repeat dose toxicity - 28 days.	NOAEL 1000 mg/kg bw/day; NOEL 150 mg/kg bw day	no	yes
Genotoxicity - bacterial reverse mutation (1)	non mutagenic	no	yes
Genotoxicity - bacterial reverse mutation (2)	non mutagenic	no	no
Genotoxicity – in vitro chromosome aberration test	non genotoxic	no	no

(1) Strains used: *Salmonella typhimurium* TA98, TA100, TA102, TA1535 and TA1537

(2) Strains used: *Salmonella typhimurium* TA98, TA100, TA1535 and TA1537, *E. Coli*WP2uvrA

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

Acute oral toxicity

One animal had wet rales at 1,2,4 and 6 hour intervals and one animal had mucoid stool at the 6 hour interval. All animals were free of observable abnormalities from the end of Day 1 to study termination.

Repeat dose oral toxicity

Female animals treated at 1000 mg/kg bw/day exhibited low white blood cell counts and slightly low alkaline phosphatase activity. Both of these were shown to be reversible with the 14 day recovery period. Low (15 mg/kg bw/day) and mid (150 mg/kg bw/day) dose females displayed statistically

significant low white blood cell and lymphocyte counts. This was possibly due to the high control mean value and was considered not to be treatment related.

Genotoxicity - bacterial reverse mutation (1)

Toxicity was seen at 50 and 1580 µg/plate in the absence of activation with strain TA1537 in the initial assay. Toxicity was seen at 1000 µg/plate in the presence of activation with strain TA1535 in the repeat assay. Since similar toxicity was not seen at higher concentrations in either case, these findings were not considered biologically relevant.

8.2. Human Health Hazard Assessment

Based on the available toxicological data, the notified polymer is expected to display low acute oral and dermal toxicity, low repeated-dose toxicity and low potential for *in vitro* mutagenicity or clastogenicity. In addition, the notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following toxicological studies were submitted:

<i>Endpoint</i>	<i>Result and Conclusion</i>
Ready Biodegradability (OECD 301F, Manometric Respirometry Test; it is not clear whether the test substance was tested in a pure or formulated form)	The average % biodegradation of the test substance was determined to be 0.58% over a 28 day duration. Thus the test substance is considered not readily biodegradable.
Ready Biodegradability (OECD 301C, Modified MITI Test; <i>Infineum C9535</i>)	The average % biodegradation by BOD and HPLC were 3 and 0%, respectively. Thus the test substance is considered not readily biodegradable.
Bioaccumulation (Carp)# “Testing methods for new chemical substances” Planning and Coordination Bureau, Environment Agency; OECD 305*, Flow-through fish test; <i>Infineum C9535</i>)	BCFs at a steady state of Level 1 (1 mg/L) and Level 2 (0.1 mg/L) were 6.4 and 12, respectively. Thus the test substance is considered not bioaccumulative.
Fish Toxicity [Rainbow trout (<i>Oncorhynchus mykiss</i>)] (OECD 203; it is not clear whether the test substance was tested in a pure or formulated form)	96 h LL50 > 1000 mg/L (based on the water-accommodated fraction (WAF) of the test substance). Thus the test substance is considered not toxic to fish at the level of its water solubility.
Algal Toxicity (<i>Selenastrum capricornutum</i>) (OECD 201; it is not clear whether the test substance was tested in a pure or formulated form)	72-h EL50 were >1000 mg/L based on growth and growth rate and the 96 h EL50 was >1000 mg/L based on cell density (based on the WAF of the test substance). Thus the test substance is considered not toxic to alga at the level of its water solubility.

A preliminary toxicity test on Orange-red killifish (*Oryzias latipes*) indicates a 96 h LC50 >125 mg/L. Again this is well above water solubility and it is expected this solution would have contained precipitates despite the use of solvents.

* Actual guideline not stated but appears to be 305C (flow through with 28 day exposure period).

9.1.1. Discussion of observed effects

Aquatic toxicity tests used a water accommodated fraction (WAF) drawn from the bottom of the stirring vessels into which the Teflon disks containing the test substance was suspended. The solution drawn appeared colourless with the test substance remaining on the Teflon disks. The WAFs were analysed for Total Organic Carbon (TOC). At the loading rate of 1000 mg/L, the TOC were 0.7138 and 1.234 mg C/L for fish and alga, respectively, indicating ~0.1% was in solution. Neither mortality nor

sub-lethal effects were observed for fish or alga at the level of water solubility of the test substance.

9.2. Environmental Hazard Assessment

The results indicate that the notified polymer is not toxic at the level of its water solubility to fish and alga, indicative of low hazard to the aquatic compartment.

10. RISK ASSESSMENT

10.1. Environment

Limited environmental release of the notified polymer is anticipated except in the case of accidental spills. The majority of the polymer will be burnt in engines along with the fuel. Any material lost as a result of spills, or remaining as residues in containers, is expected to be recovered and disposed of by incineration. The ecotoxicity data provided and likely low release to water indicate that there is unlikely to be an environmental risk in the aquatic compartment under the proposed use pattern.

The notifier expects that the new fuel additive is unlikely to have implications for emissions on air pollution or greenhouse gases.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low due to limited exposure and the expected low toxicity.

10.3. Public Health

Members of the public may make incidental contact with diesel fuel containing the notified polymer. However, the risk to public health will be negligible due to the expected low toxicity and because the notified polymer is present at low concentrations. As it is expected that the notified polymer will be destroyed within the combustion engine, public exposure to the notified polymer from exhaust emissions is expected to be negligible.

11. Risk Assessment Relating to Extension Applicant

Extension Applicant:

Use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to significantly change the environmental and health impacts. Therefore there are no changes required in the risk assessment.

12. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

12.1. Environmental Risk Assessment

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

12.2. Human Health Risk Assessment

12.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

12.2.2. Public health

There is Negligible Concern to public health based on its reported use pattern.

13. MATERIAL SAFETY DATA SHEET

13.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the

information on the MSDS remains the responsibility of the applicant.

14. 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 by incineration

Emergency procedures

Land spill

- If the notified polymer is spilled outside the workplace, the liquid should be prevented from entering sewers, watercourses or low areas. The liquid should be contained with sand or earth and recovered by pumping or by absorption into sand or earth before being disposed in an approved manner.

Water spill

- The spill should be removed from the surface of the water by skimming or with suitable absorbent. If appropriate, sinking and/or dispersants may be used in non-confined waters.

14.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.