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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Tego Antifoam MR 465 and Polymer in Tego Antifoam MR 467

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 Heritage.

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FULL PUBLIC REPORT

Polymer in Tego Antifoam MR 465 and Polymer in Tego Antifoam MR 467

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

International Sales and Marketing (ABN: 36-467-259-314)

262 Highett Road

Highett, Victoria, 3190

and

Lubrizol International Inc. (ABN: 52-073-495-603)

28 River St

Silverwater, NSW, 2128

and

Afton Chemcial Asia Pacific LLC (ABN: 99-109-644-288)

Level 9/20 Berry St North Sydney, NSW, 2060

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name

CAS No.

Other Names

Molecular and Structural Formulae

Molecular Weight (NAMW and WAMW)

Polymer Constituents

Spectral Data

Residual Monomers/Impurities

Purity

Degradation Products

Use Details

Import Volume

Site of Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Hydrolysis as a function of pH [List]

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

USA (2003)

Canada (2003)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Tego Antifoam MR 465, Tego Antifoam MR 467.

OTHER NAME(S)

Tego Anitfoam D 515 XP, Tego Antifoam D 515, Tego XP 9011, Tego Antifoam MR 500.

Polymer in HiTEC® 4620 Diesel Fuel Additive Polymer in LUBRIZOL® 9570Z

METHODS OF DETECTION AND DETERMINATION

Remarks No specific methods available.

3. COMPOSITION

DEGREE OF PURITY >70%

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. The notified polymer will be imported in products in bulk in drums, IBCs or ISO containers at up to 85%.

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

Year	1	2	3	4	5
Tonnes	30-100	30-100	30-100	30-100	30-100

USE

Antifoam additive for non-aqueous media (fuels).

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will be stored at warehouses in Melbourne and Sydney.

TRANSPORTATION AND PACKAGING

The imported liquid product containing the notified polymer (at a concentration of up to 85% w/w) will be imported through Sydney and Melbourne ports in 200 kg steel drums or ISO tainers and transported by road from the wharf for storage at third party storage facilities. The product containing the notified polymer will then be transported in either drums, IBCs (1500 and 1000 kg) or ISO tainers to the refineries by road for use in automated dilution equipment.

5.2. Operation description

The notified polymer is not currently reformulated, however there exists potential to reformulate. The operation description provided by the notifier for reformulation below is consistent with the potential customer base.

Reformulation

During the reformulation process, the imported product containing the notified polymer (up to 85%) will be transferred to a mixing tank via automated pumps. The mixing process is automated and occurs in a closed system. QC sampling may occur during or immediately after mixing. Once the mixing is finished, the resultant product containing the notified polymer (up to 3%) is automatically transferred to a storage tank using dedicated piped lines or filled into drums, tank trunks or ISO tainers. Drumming of the finished product directly from the blending tank or from storage tanks can be automated or can involve the manual connection and disconnection of filling lines.

Blending

At the refinery, the imported/reformulated product containing the notified polymer (up to 3%) will be mixed with fuel during the loading of the tank truck with refined fuel. The notified polymer will be present in the blended fuel at a concentration of <0.001%. The imported/reformulated product containing the notified polymer will be injected together with refined fuel into the tank truck to form the finished fuel before delivery to petrol stations for sale. The pumping and injection operation are carried out automatically in a closed pipeline system and the equipment only requires changeover on each drum. The operation will be carried out by 1-2 workers at each customer's site and will often be carried out by the same workers (the tank truck driver) who would normally load the tank truck. The facilities will be well-ventilated.

Distribution and use

The blended fuel containing the notified polymer will be distributed by road tankers for delivery and sale at retail fuel outlets.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Transport	20	unknown	unknown
Storage	24	unknown	unknown
Reformulation	unknown	unknown	unknown
Blending (operations personnel)	100	1	10/week

Exposure Details

Transport and Storage

During transport of the product (containing the notified polymer), workers might come into dermal and ocular contact with up to 85% the notified polymer through accidental leaks and spillages of the drums and containers.

Reformulation

During the automated reformulation process, dermal and ocular exposure to the notified polymer at up to 85% is possible due to splashes and spillages arising during certain mixing and packaging processes, equipment cleaning and maintenance. For example, when pumping and metering the imported product into mixing tanks and packaging workers when connecting/disconnecting transfer lines may be potentially exposed to the notified polymer at a concentration up to 85% and 3% respectively. Exposure of cleaning, sampling and testing workers are anticipated to be less frequent and in smaller quantities.

Blending

During the automated blending process, worker exposure to the notified polymer at up to 1% is expected to be negligible as compared to the inhalation exposure to the other more volatile components of the fuel. Dermal and ocular exposure to up to 3% notified polymer may occur as a result of accidental spills and splashes. Appropriate containment procedures (such as catching pans) and engineering controls (local exhaust ventilation) are expected to be in place at the refineries. Workers will wear personal protective equipment such as safety glasses, gloves and overalls. Exposure to the notified polymer in the final blended fuel will be <0.001%.

Fuel use

While the notifier provides no specific details, petrol station workers may be potentially exposed to diluted notified polymer (<0.001%) in fuel during fuel handling activities and maintenance of automotive fuel systems.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The automated nature of the blending and mixing procedures in a closed pipeline system, suggests that containers may be flushed during the procedure, thus limiting any release to the environment from container residues. Any remaining residue is likely to be sent to a reconditioning facility, where

it is to be cleaned with mineral oil and the residues disposed of by incineration. There is minimal risk of environmental exposure from storage and reformulation facilities, if storage, handling and spill procedures are followed.

RELEASE OF CHEMICAL FROM USE

The notified polymer is used as a fuel additive, where the vast majority of the product will be released to the environment after being combusted with the fuel, in an internal combustion engine. It is expected by the notifier that the majority of the additive will be completely combusted to form oxides of carbon, water vapour and silica of unspecified size and morphology. No indication has been given to the effect on vehicle emissions.

In a worst-case scenario assuming 10 mL is spilled with every vehicle fill (average tank size 40 L) the rate of spillage would be 0.025%. From the maximum imported amount of 100 tonnes the resulting amount from incidental spills would be 25 kg. These spills would occur throughout Australia at consumer petrol stations.

5.5. Disposal

Minor spills at domestic petrol stations are likely to fall to the ground. The more volatile fuel will evaporate, leaving the notified polymer behind. The polymer is moderately soluble and over time some may be washed to storm water drains. It will slowly undergo degradation by biotic and abiotic processes to form oxides of carbon, water vapour and silica.

The vast majority of the notified polymer will be consumed during its use. However, minor amounts arising from accidental spills and container residues are likely to be disposed of by incineration, where the polymer will be combusted to form oxides of carbon, water vapour and silica.

5.6. Public exposure

Dermal and ocular exposure to <0.1% notified polymer may occur during the filling operation at the petrol station. However, little exposure will occur due to the low concentration of the notified polymer in finished fuels.

6. PHYSICAL AND CHEMICAL PROPERTIES

The following tests were performed on TEGO Antifoam D 515, which contains 100% of the notified polymer.

Appearance at 20°C and 101.3 kPa Clear yellow-brown solution

Melting Point -65--68°C

METHOD OECD TG 102 Melting Point/Melting Range.

EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.

Remarks Phase transition determined visually.

Statement of GLP.

TEST FACILITY RCC (2005a)

Boiling Point >360°C (Decomposes before boiling)

METHOD OECD TG 103 Boiling Point.

EC Directive 92/69/EEC A.2 Boiling Temperature.

Remarks An exothermic reaction was observed starting at about 360°C was caused by

decomposition of the test item.

Determined by Differential Scanning Calorimetry.

Statement of GLP.

TEST FACILITY RCC (2005a)

Density $1022 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$

METHOD OECD TG 109 Density of Liquids and Solids.

EC Directive 92/69/EEC A.3 Relative Density.

Remarks Determined using an oscillating densimeter.

Statement of GLP.

TEST FACILITY RCC(2002b)

Vapour Pressure

Not Determined.

Remarks Due to high molecular weight significant vapour pressure is not expected.

Water Solubility 3.22 g/L at 20°C

METHOD OECD TG 105 Water Solubility.

EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Flask Method: Approximately 6.3 g of test item was transferred into each of 6

Erlenmeyer flasks. 500 mL of water was added and pH adjusted to 7.0. Duplicate analyses were performed at 24, 48 and 72 hours at 30°C, followed by 24 hours at 20°C. 200 mL of mixture was filtered (0.2 μ m) and freeze dried. The dried test item was analysed by HPLC. The test sample shows surprisingly high solubility given the large proportion of hydrophobic groups and the difficulty in achieving a stable

solution at 100 mg/L for the acute toxicity aquatic invertebrate test.

TEST FACILITY RCC (2002c)

Hydrolysis as a Function of pH

Not Determined.

Remarks There are no groups present that are expected to undergo hydrolysis in

environmental conditions (pH 4-9).

Partition Coefficient (n-octanol/water) log Pow = 2.2 at 20°C (Main Peak)

 $\log Pow = 2.0$ at 20°C (Shoulder)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).

EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks Duplicate determinations were made using HPLC with UV/VIS detector, reverse

phase column and an aqueous mobile phase. The notified polymer eluted in the

middle of the 6 reference peaks.

TEST FACILITY RCC (2005a)

Adsorption/Desorption

Not Determined.

Remarks The notified polymer is determined to be at the lower end of readily water soluble.

There are indications from the polymer structure and anecdotal evidence of the polymer's solubility from the acute toxicity aquatic invertebrate test that the polymer could be classified as moderately water soluble. Accordingly the polymer would show some affinity for adsorbing on soil but would likely to be leached to

aqueous compartment over time.

Dissociation Constant

Not determined.

Remarks The notified polymer contains functionalities which are expected to display typical

weak acidity with pKa values of approximately 10. Accordingly the polymer will remain in predominantly the non - ionised form throughout the environmental pH

range of 4-9.

Flash Point 141°C at 101.3 kPa (closed cup method)

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Remarks The notified chemical is classified as a C1 combustible liquid according to

NOHSC National Code of Practice for the Storage and Handling of Workplace

Dangerous Goods (NOHSC 2001).

Statement of GLP.

TEST FACILITY RCC (2005b)

Flash Point 62°C at 101.3 kPa (for the product containing the notified

polymer)

Flammability Limits Not determined

Remarks Based on the flash point the notified chemical is not classified as flammable

according to the Australian Dangerous Goods classification (FORS, 1998)

Autoignition Temperature 375°C

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks Statement of GLP TEST FACILITY RCC (2005c)

Explosive Properties Not Explosive

Remarks Expert Statement.

According to UN recommendation criteria, the notified polymer is not classified as

explosive.

TEST FACILITY RCC (2005d)

Reactivity Stable under normal conditions of use

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	Result and Assessment Conclusion
Rat, acute oral LD50	>2000 mg/kg bw, low toxicity

7.1. Acute toxicity - oral

TEST SUBSTANCE Notified polymer (up to 20%)

OECD TG 423 Acute Oral Toxicity - Acute Toxic Class Method. **METHOD**

EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class

Method.

Species/Strain Rat/HanRcc:WIST (SPF) Vehicle Polyethylene glycol

Remarks - Method Limit test used. No significant protocol deviations. Statement of GLP.

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
1	3	2000	0/3
2	3	2000	0/3

LD50 >2000 mg/kg bw Signs of Toxicity None.

Effects in Organs Congestions in the lungs was noted in two animals of the first treated group whereas grey/white foci were noted on the left kidney in two

animals of the second treated group at necropsy.

Remarks - Results There were no deaths or notified polymer related clinical signs or

remarkable body weight changes during the study period. The LD50 cutoff estimated using the flow chart in Annex 2d of the OECD TG 423

would be ≥5000 mg/kg bw.

CONCLUSION The notified polymer is of low toxicity via the oral route.

RCC (2005e) TEST FACILITY

8. ENVIRONMENT

8.1. Environmental fate

Remarks - Method

No environmental fate data were submitted. The notifier's submission that the polymer is not biodegradable is accepted on the basis of tests on biodegradability of analogous polymers. Similarly the submission that the polymer should not bioaccumulate is accepted on the basis of the polymer's high molecular weight and moderate water solubility.

8.2. Ecotoxicological investigations

8.2.1. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test 48 hour static test.

EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - 48 hour

NOEC.

Species Daphnia magna

Exposure Period 48 hours

Auxiliary Solvent Suspension

Water Hardness 250 mg/L (as CaCO₃)
Analytical Monitoring Test concentrations by HPLC

The results were based on a range finding test. Four replicates of five daphnids each in 50 ml of water were prepared for both the test sample and control. The test medium was prepared by dispersing 201.1 mg of test item completely in 2000 mL of test water using intense stirring for 30 minutes at room temperature. Analysis of test material was carried out at a nominal concentration of 100 mg/L at 0, 24 and 48 hours at a temperature of 20 - 21°C with 16 hour light to 8 hour dark photoperiod (30 minute transition period) and light intensity of 570 - 740 Lux. The mean measured concentration of the four replicates was 73 mg/L. Turbidity and settling of the test material was noticed, and the insolubility of the polymer is likely to account for the discrepancy between the

nominal and measured concentrations.

RESULTS

Concentration mg/L		Number of D. magna	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	20	0	0
100	73	20	0	0

LC50 >100 mg/L at 48 hours (nominal)

NOEC = 100 mg/L at 48 hours

replicates.

CONCLUSION The test substance is not toxic to Daphnia to the limit of its solubility.

TEST FACILITY RCC (2005f)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported and is blended as a fuel additive with other components of the fuel. Therefore most of the notified polymer will be combusted with the fuel, in an internal combustion engine. The combustion products will be oxides of carbon, water vapour and silica of unspecified size and morphology. Environmental exposure of 25 kg per annum distributed Australia wide at consumer petrol stations, is expected to arise from incidental spills arising from refuelling of vehicles. The polymer is moderately water soluble and is likely to be leached over time into the aquatic environment. It is likely to slowly undergo degradation by biotic and abiotic processes to form oxides of carbon, water vapour and silica.

No indication of the residual amount in transport containers is indicated. However, it is expected that a portion of this will be recovered during the reformulating process, with the remainder being sent to a reconditioning facility where it is, recovered with mineral oil and the residues disposed of by incineration.

Due to the usage pattern no PEC can be calculated.

No indication has been given to the effect on vehicle emissions.

9.1.2. Environment – effects assessment

The notified polymer contains reactive functional groups but is not expected to have significant effects on the aquatic environment. The single test provided by the notifier indicates there was no toxicity up to the limit of the polymer's solubility (100 mg/L nominal).

9.1.3. Environment – risk characterisation

The vast majority of the notified polymer will be combusted with fuel, in an internal combustion engine. The combustion products will be oxides of carbon, water vapour and silica of unspecified size and morphology. Given the low amount of the notified polymer present in the fuel, it may not have significant implications for fuel emissions but no data are available, including effects on particulates.

Small quantities arising from accidental spills and container residues are expected to be incinerated and will likewise combust to form oxides of carbon, water vapour and silica. It is unlikely that any significant quantities of the polymer will enter the aquatic environment.

The environmental risk is expected to be low as the exposure of the notified polymer to the environment is expected to be low. Furthermore, it was demonstrated that it was non toxic to daphnia in the single toxicology test performed on aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified polymer is not expected to be significantly volatile, spills and splashes resulting in dermal and/or ocular contact are the most likely exposure scenario. Exposure is most likely to occur during transfer of the product containing the notified polymer between storage/transport containers and blending facilities, and fuel during the transfer of blended fuel from the blending unit to storage and to subsequent transport, and during the fuelling of vehicles with the blended fuel. Exposure is expected to be low due to the largely automated processes involved and the use of PPE. Exposure of workers involved in blending and transfer of the fuel will be further limited by the low concentration of the notified polymer (3% and <0.001%, respectively).

9.2.2. Public health – exposure assessment

Public exposure is not expected to occur unless there is an accidental spill and/or release of either the fuel additive or the blended fuel. Public exposure is most likely to occur during

refuelling of vehicles at petrol stations. Dermal and ocular exposure may occur, however given the low concentration of the notified polymer (<0.001%) and the minimal direct contact with fuel under normal circumstance public exposure is expected to be minimal.

9.2.3. Human health – effects assessment

The notified polymer is of low acute oral toxicity. Based on this study, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The notified polymer contains a high concern functional group whose reactivity in biological settings cannot be ruled out. However the FGEW for this functional group is >1000 reducing the likelihood of exposure to that functional group. In addition the notified polymer contains <5% low molecular weight species (<1000). Typically, polymer species with an MW>1000 are unlikely to cross biological membranes and thence the polymer is likely to be of low hazard.

Emissions (silicon dioxide and carbon dioxide) generated from combustion of the notified polymer is not expected to be significant given the low percentage of the notified polymer in fuel.

9.2.4. Occupational health and safety - risk characterisation

The product containing the notified polymer is not hazardous but is a component of products that are classified as hazardous according to the criteria of NOHSC.

Due to the limited exposure expected and the likely low hazard of the notified chemical the risk to workers is expected to be low.

9.2.5. Public health - risk characterisation

Due to the minimal exposure expected and the likely low hazard of the notified polymer the risk to the public is expected to be low.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the notified polymer is not classified as hazardous using the Globally Harmonised System for the Classification and Labelling of Chemicals

(GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of two products containing the notified polymer were provided by two notifiers and were assessed in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

The following amendments are recommended for the MSDS for the product HiTEC 4620 Diesel Fuel Additive containing the notified polymer:

Statement of Hazardous Nature

The following amendments are recommended for the MSDS for the product TEGOPOLYMER containing the notified polymer:

- Australian Company Contact Details in Section 1; and
- Statement of Hazardous Nature

11.2. Label

The label for the notified polymer and products containing the notified polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Gloves (impervious)
 - Eye protection
 - Coveralls
- Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- The notified chemical as introduced should be handled consistent with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.
- 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.

Storage

• The notified chemical as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

Emergency procedures

 Spills or accidental release of the notified polymer should be handled by physical containment and subsequent adsorption onto adsorptive material. The adsorbed material should be disposed of by authorised incineration.

12.1. Secondary notification

The Director of Chemical Notification and Assessment 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 present in the fuel at >0.1%;
- (2) Under Section 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.

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