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

FULL PUBLIC REPORT

Z-105

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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FULL PUBLIC REPORT**Z-105****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lubrizol International, Inc. (ABN 52 073 495 603)
28 River Street
Silverwater NSW 2128

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical name, molecular formula, structural formula, number average molecular weight, molecular weight, means of identification, additive/adjuvants, purity, use details, import volume, weight percentage and ingredient, residual monomers, low molecular weight polymer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Vapour pressure, particle size, water solubility, hydrolysis as a function of pH, partition co-efficient, adsorption/desorption, dissociation constant, flash point, flammability limits, auto-ignition temperature, explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Nil

NOTIFICATION IN OTHER COUNTRIES

Nil

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-105 (product containing the notified polymer Z-105 at 95% concentration in mineral oil)

CAS NUMBER

Not assigned

MOLECULAR FORMULA

Not assigned

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

Reference NMR, IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Under normal use circumstances, there would be no natural loss of monomers or reactants from the notified polymer.

DEGRADATION PRODUCTS

The notified polymer is relatively stable. It is not expected to de-polymerise under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Slightly viscous amber coloured liquid (solution in mineral oil)

Property	Value	Data Source/Justification
Melting Point/Freezing Point (Pour Point)	<20.15°C	Measured
Boiling Point	--	Not determined
Density	929 kg/m ³ at 20°C	Measured
Vapour Pressure	Not determined	Expected to have very low vapour pressure, based on the high molecular weight of the notified polymer.
Water Solubility/Extractability	Total extractabilities: 35-262 mg/L at pH 2, ≤ 50.0 mg/L at pH 7 and ≤ 30 mg/L at pH 9 at 20°C. Solubilities: ≤ 188 mg/L at pH 2, ≤ 125 mg/L at pH 7 and ≤ 33.1 mg/L at pH 9 at 20°C.	The water solubility results are high due to the presence of insoluble lumps in all of the analysed samples. The notified polymer is expected to have limited solubility in water, based on its hydrophobic structure.
Hydrolysis as a Function of pH	Not determined	Test was attempted and no data on the hydrolysis properties were obtained. The notified polymer was insoluble in water at pH 1.2, 4 and 7. No degradation occurred at pH 9. The notified polymer has hydrolysable functionalities but in environmental pH (4-9), it is expected to hydrolyse very slowly.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition to n-octanol from water, based on its mainly hydrophobic structure and limited water solubility.
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb strongly to soil, based on its mainly hydrophobic structure and limited water solubility.
Dissociation Constant	pK _{a1} = 15.52, pK _{a2} = 14.40	Estimated using ACD/I-Lab Web Service (ACD/PK _a 8.03). The notified polymer is not expected to be ionised in the environmental pH range of 4-9.
Particle Size	Not determined	As the notified polymer will be sold as viscous liquid (Z-105), the particle size test is not applicable.
Flash Point	Not determined	Expected to be >100°C, based on similar material.
Flammability	Not determined	The product is a viscous liquid.
Autoignition Temperature	Not determined	Autoignition temperature would be largely based upon the diluent oil
Explosive Properties	Not expected to be explosive.	Based on chemical structure of the notified polymer.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified polymer is not an oxidiser and is considered to be stable and not reactive.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table, the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical/polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia and will be imported as a 95% solution in mineral oil.

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>	10-30	10-30	100-300	100-300	100-300

PORT OF ENTRY

Not known.

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will be imported as a 95% solution in mineral oil for use as an additive package for automotive gear oil. Further blending and packaging of automotive gear oil containing the notified polymer will occur at different sites in Australia.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia as a 95% solution in mineral oil in 55-gallon drums or isotainers. The drums/isotainers would be transported directly to the customers blending facilities for blending.

USE

The notified polymer will be used as a viscosity modifier in automotive gear oil at concentrations of <20%.

OPERATION DESCRIPTION

The notified polymer will be imported as a 95% solution in mineral oil and will be further processed at customer's blending facilities.

A typical formulation operation would involve blending the concentrate containing the notified polymer with diluent oil and additional additives to form an additive package. The concentrate containing the notified chemical will be decanted from the drums or isotainers to the tanks where it would be mixed with other additives and diluent oil. The finished additive package would contain <20% of the notified polymer. The finished additive package would be pumped into drums, isotainers or smaller containers for transport. All these operations are expected to be carried out in automatically or semi-automatically in a closed system. Packaging equipment is also expected to be automated and housed within or near the blending operation area. The blending facility is expected to be well ventilated.

The finished additive package containing the notified polymer will be supplied in bulk to various users such as car manufacturers, mechanical workshops etc. Additionally, it may also be supplied in smaller containers for use in service applications through garages or sold to the public for DIY use.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

The number and category of workers involved in the use of the notified polymer is not available. However, it is expected that the products containing the notified polymer would be used by workers in mechanical workshops and vehicle manufacturing factories. Therefore, a considerable number of workers are expected to be involved in the transportation, distribution and the use of products containing the notified polymer.

EXPOSURE DETAILS

Transport and storage workers are not likely to be exposed to the notified polymer except in the case of an accident involving damage to the packaging.

The blending facility is expected to be well ventilated and fully automated/semi-automated. Therefore, exposure during blending will be negligible and will mostly be limited to transfer operations in mixing vessels, during coupling, residues in lines, and occasionally from leaks and spills. Dermal contact would be the main route of occupational exposure. Some inhalation exposure could occur if mists are generated during blending processes. Workers are expected to take usual safety measures to wear protective aprons, gloves and boots as appropriate during various procedures to minimise exposure to the notified polymer.

Workers may be exposed to engine oils containing the notified polymer at less than 20% during use in vehicle manufacturing or mechanical workshops.

At car manufacturers, the finished gear oil is expected to be added to vehicles using a mechanical transfer and exposure is unlikely. There is a potential for dermal exposure from drips, spills and splashes as well as from handling equipment contaminated with the finished gear oil. Workers are expected to wear appropriate personal protective equipment (PPE) to minimize dermal exposure.

At mechanical workshops, professional users such as mechanics may experience dermal or ocular exposure to the final product containing the notified polymer at <20%, when adding the gear oil to the automobile and other machinery. The risk of both dermal and ocular exposure may be reduced by wearing appropriate PPE.

6.1.2. Public exposure

The end-use for the notified polymer will be in automotive gear oil at concentrations of <20%. Therefore, once the gear oil is added to the automatic transmission system, the general public will not be exposed to the notified polymer in the gear oil since the automatic transmission system operates as a closed system. Furthermore, public exposure during the addition of gear oil is also expected to be minimal as most gear oils are added and/or replaced by certified mechanics.

However, DIY users may experience inadvertent dermal and ocular exposure to final products containing <20% of the notified polymer when adding and/or replacing engine oil of their vehicles. Overall, public exposure is expected to be limited due to its infrequent use and concentration (<20%) of the notified polymer in finished gear oil additive package.

6.2. Human health effects assessment

The result from toxicological investigation conducted on the notified polymer is summarised in the table below. Details of this study can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

No data were available to assess toxicokinetics, metabolism and distribution of the notified polymer. Based on the high molecular weight (>1000 Da), negligible concentration of low molecular weight species, and limited water solubility, potential for absorption of the notified polymer across biological membranes is expected to be limited.

Acute toxicity

No data were available to assess the acute toxicity potential of the notified polymer.

Irritation and Sensitisation

No data were available to assess eye or skin irritation and skin sensitisation potentials of the notified polymer.

Repeated Dose Toxicity

No data were available to assess the repeat dose toxicity potential of the notified polymer.

Mutagenicity

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation test.

Health hazard classification

Based on the limited data provided, the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation**6.3.1. Occupational health and safety**

The notified polymer, based on submitted study, is not expected to be genotoxic. As studies were not submitted for other toxicological end-points, it is not possible to define hazards associated with the use of the notified polymer. However, based on the high molecular weight (>1000 Da), negligible concentration of low molecular weight species, and limited water solubility, potential for absorption of the notified polymer across biological membranes is expected to be limited. Therefore, the notified polymer is not expected to present significant health hazards to workers during its use.

Workers may be exposed to the notified polymer at less than 20% concentration during blending and change/addition of gear oil in vehicles manufacturing or mechanical workshops. However, the level of exposure is not expected to be significant considering the concentration of the notified polymer in these products (<20%), control measures expected to be used including engineering controls, automated processes, and the use of PPE. Therefore, overall risk of exposure to the notified polymer will be low and not considered to be unacceptable to the health of workers.

6.3.2. Public health

The notified polymer will be used in automotive gear oil at concentrations of <20%. Therefore, once gear oil containing the notified polymer is added to the vehicle, the general public will not be exposed to the notified polymer. Furthermore, exposure during the addition of gear oil to vehicle is also expected to be minimal as the gear oils are mostly added and/or replaced by certified mechanics.

DIY users may experience inadvertent dermal and ocular exposure to final products containing <20% of the notified polymer when adding and/or replacing gear oil of their vehicles. Exposure would be minimised if users wear gloves, goggles and a long sleeved shirt. Overall, the risk of public exposure is expected to be limited due to its infrequent use, low volume handled, and concentration of the notified polymer in finished gear oil. Therefore, the risk of exposure to general public is low and not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a > 95% solution in mineral oil for application in gear oil product in Australia. No significant release is expected from the transportation and storage of the notified polymer.

Further blending of the notified polymer with diluent oil and additional additives (to form an additive package), including pumping of the concentrate notified polymer to the customer's storage tank and the pumping of the finished additive package into containers for transport to final user sites, will be carried out in an automatic or semi-automatic enclosed system. Any residual amount of notified polymer in transport vessels or equipment is expected to be recovered using a sump system and recycled. No significant release is expected from this process.

RELEASE OF CHEMICAL FROM USE

The gear oil will be used in commercial garages and original equipment manufactures. Gear oils are changed infrequently and it is assumed that skilled tradesmen will be undertaking almost all maintenance of equipment at car manufacturers, mechanical workshops etc. A very small proportion of gear oil is expected to be used by DIYs. No significant release of gear oil containing the notified polymer is expected from processes of new oil filling and used oil removing from gear boxes. During the use of the finished gear oil containing the notified polymer, the product will be contained within the enclosed gear boxes and the release of the notified polymer is expected to be low.

RELEASE OF CHEMICAL FROM DISPOSAL

Any used oil generated from engine repair or changeover is expected to be disposed of in accordance with State/Territory regulations which are most likely to go to sealed landfill or recycled to be re-used as burner oil (e.g. kilns and industrial burners).

Residual amount of the notified polymer in the empty drums or isotainers is estimated to be < 1% of the imported volume and will be easily removed by washing with mineral oil at the reconditioning facility for proper disposal or reuse.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is not expected to be bioaccumulative or bio-available to the aquatic organisms due to its high molecular weight and expected limited release to the water environment. Most of the notified polymer will be either thermally decomposed during use as a component in gear oil or in re-use of used oils. A small amount of the notified polymer is expected to be sent to landfill as residues in containers or a component of waste oil. Either via thermal decomposition or in landfill, the notified polymer is expected to be degraded into water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer has a molecular weight of > 1000 and does not contain any functional groups of high concern and therefore, it is considered to have low concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

A PNEC has not been calculated since no ecotoxicity data are available for the notified polymer and it is expected to have very low exposure to the aquatic environment.

7.3. Environmental risk assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) cannot be calculated since neither PEC nor PNEC has been calculated due to the low exposure expected from the reported use pattern and the lack of toxicity data.

The notified polymer is not considered to pose an unacceptable risk to the aquatic environment based on both its molecular structural features (high molecular weight and no functional groups of concern) and reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited data, the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

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 and diluted for use:
 - Chemical resistant gloves
 - Coveralls
- 1. Safety glasses

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 chemical 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

Disposal

- The notified chemical should be disposed of to landfill.

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 a viscosity modifier in automotive gear oil, or is likely to change significantly;
 - if concentration of the notified polymer is >20% in gear oil used by public;
 - the amount of chemical being introduced has increased from 300 tonnes, or is likely to increase, significantly;
 - [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.

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 provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Physical and chemical properties were conducted on a product containing >95% notified polymer.

Melting Point/Freezing Point <20.15°C
(Pour Point)

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	As the test material was complex polymeric liquid mixture, it was considered that pour point testing would be most applicable.
Test Facility	Harlan Laboratories Ltd. (2009a)

Density 929 kg/m³ at 20 ± 0.5°C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using the pycnometer method.
Test Facility	Harlan Laboratories Ltd. (2009a)

Water Solubility/extractability Total extractabilities: 35-262 mg/L at pH 2, ≤ 50.0 mg/L at pH 7 and ≤ 30 mg/L at pH 9 at 20°C.
Solubilities: ≤ 188 mg/L at pH 2, ≤ 125 mg/L at pH 7 and ≤ 33.1 mg/L at pH 9 at 20°C.

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water with reference to “NSN Technical Guidance Series, OECD Test Guideline 120 for Water Extractability of Polymers, Final Draft Version- June, 2007”.
Remarks	Flask Method. A certain amount (2.5 g) of the notified polymer was mixed with 250 mL water (triplicates) at pH 2, 7 and 9. The mixtures were shaken for 24 hours at 20±2°C and centrifuged for further analyses of the supernatant. The supernatant solutions were extracted using dichloromethane and analysed in solutions of tetrahydrofuran by a GPC method. The overall total extractables were gravimetrically determined. The higher than expected and variable test results were due to the non-heterogeneous nature of the excess test substance finely dispersed in the analysed sample supernatants.
Test Facility	Harlan Laboratories Ltd (2009a)

Dissociation Constant pK_{a1} = 15.52, pK_{a2} = 14.40

Method	ACD/I-Lab Web Service (ACD/PK _a 8.03)
Remarks	The pK _a values were estimated using the software. The notified polymer is not expected to be ionised in the environmental pH range of 4-9.
Test Facility	Harlan Laboratories Ltd (2009a)

Hydrolysis as a Function of pH Not determined

Method	Not reported
Remarks	To test the stability of the notified polymer in water at different pH, the notified polymer was mixed with buffers of pH 1.2, 4, 7 and 9 and shaken at 40°C. After one hour, a small aliquot was removed for GPC analysis. The mixtures were further shaken at 40°C for 24 hours (for the pH 1.2 solution) or 2 weeks (for the pH 4, 7 and 9 solutions) for GPC analysis of the solutions. The notified polymer was found to be insoluble in all but one test solution (pH 9 aliquot). GPC analysis of this solution indicates no reaction or degradation of the notified polymer. No further test was conducted. Therefore, the half life for hydrolysis of the notified polymer was not determined.
Test Facility	Lubrizol (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer (>95% notified polymer)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA ⁻
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone-induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviations. A preliminary toxicity assay was carried out to determine the toxicity of the test material. Test 1 was performed using the direct plate incorporation method while test 2 was performed using the pre-incubation method. The positive control chemicals n-ethyl-N'-nitro-N-nitrosoguanidine (ENNG), 9-aminoacridine (9AA), 4-nitroquinoline-1-oxide (4NQO) were used in the series of plates without S9-mix. In addition, 2-aminoanthracene (2AA) and benzo(a)pyrene were used as a positive controls in the series of plates with S9-mix.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	>5000	>5000	5000*	Negative
Test 2	Not performed	>5000	5000*	Negative
<i>Present</i>				
Test 1	>5000	>5000	5000*	Negative
Test 2	Not performed	>5000	5000*	Negative

*A precipitate (oily in appearance) was noted at 5000 µg/plate. However, this observation did not prevent the scoring of revertant colonies.

Remarks - Results	The vehicle control plates gave counts of revertant colonies within the normal range. All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies, both with and without metabolic activation. Thus, the sensitivity of the assay and the efficacy of the S9-mic were validated. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan Laboratories Ltd (2009b)

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