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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-115

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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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 Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual monomers, impurities, use details, manufacture/import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: adsorption/desorption.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Currently undergoing notification in several countries.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-115

OTHER NAME(S)
OS255903, OS255911

MOLECULAR WEIGHT
Mn >1000 Da

ANALYTICAL DATA
Reference NMR, ESI-MS, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Under normal conditions of use, the notified polymer is not expected to lose monomers or reactants.

DEGRADATION PRODUCTS
The notified polymer is not expected to depolymerise under normal conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Dark, viscous liquid

Property	Value	Data Source/Justification
Pour Point	33 ± 3°C	Measured
Boiling Point	approx. 382 – 450°C at 101.3 kPa	Measured
Density	850 kg/m^3 at 20°C	Measured
Vapour Pressure	7.8 x 10^{-7} kPa at 25°C	Measured
Water Solubility	≤ 75.1 ×10^{-3} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to be hydrolytically stable based on its low water solubility and the absence of readily hydrolysable functions
Partition Coefficient (n-octanol/water)	log Pow > 9.4	Measured
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge based on its high molecular weight and the presence of potentially cationic functional groups
Dissociation Constant	Not determined	The notified polymer has weakly basic functions and is not expected to ionise significantly in the environmental pH range (4-9)
Flash Point	221 ± 2°C (closed cup)	Measured
Flammability	Not expected to be highly flammable	Estimated
Autoignition Temperature	352 ± 5°C	Measured
Explosive Properties	Not predicted to be explosive	Estimated 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 stable and non-reactive under normal conditions of use.

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 polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia in an additive package containing 2-4% of the notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 100	< 100	< 100	< 100	< 100

PORT OF ENTRY
Not known

IDENTITY OF MANUFACTURER/RECIPIENTS
Reformulation and use of products containing the notified polymer will occur at several sites in Australia.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in isotainers, drums or smaller containers. It will then be transported to

the facilities of customers for reformulation. At the customer facilities, it may be pumped into storage tanks prior to reformulation.

USE
The notified polymer will be used as a dispersant in diesel engine oil at concentrations up to 0.6%. It will mainly be used by professional mechanics, though a small proportion may also be used by Do-It-Yourself (DIY) users (expected to be no more than 10% of the total use).

OPERATION DESCRIPTION
The notified polymer will be imported into Australia in a diesel engine oil additive product at concentrations of 2-4%. The additive product containing the notified polymer will be further processed at the reformulation facilities of customers.

Reformulation
A typical reformulation operation will involve blending the diesel engine oil additive product containing the notified polymer (2-4% concentration) with diluent oil and additional additives. After blending, the finished diesel engine oil product will contain the notified polymer at concentrations up to 0.6%. It will then be pumped into containers (drums, isotainers or smaller containers) for transport/sale. All operations are carried out automatically or semi-automatically in a closed system. Furthermore, the facility is expected to be well ventilated.

End use
The finished diesel engine oil product (up to 0.6% notified polymer) will be used by workers in vehicle manufacturing and mechanical workshops. This will mainly involve workers transferring the product to vehicles engines and other machinery.

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, reformulation and use of products containing the notified polymer.

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

Reformulation
Dermal and ocular exposure of workers to the notified polymer (concentrations of up to 4%) may occur during reformulation operations. Such exposure may be to residues present in transfer lines, and spills and leaks that may arise during the transfer to mixing vessels and coupling of transfer lines. Some inhalation exposure could occur if mists are generated during blending processes. The potential for exposure to occur is expected to be lowered by the ventilation and automated or semi-automated procedures expected to be in operation at the reformulation facilities. In addition, workers are expected to take usual safety measures, such as wearing protective aprons, nitrile or neoprene gloves, and boots as appropriate during reformulation procedures to further minimise exposure to the notified polymer.

End use
Workers may be exposed to engine oils containing the notified polymer at up to 0.6% during use in vehicle manufacturing or mechanical workshops.

At car manufacturers, the finished diesel engine oil is expected to be added to engines using a mechanical transfer process. There is potential for dermal exposure of workers from drips, spills and splashes as well as from handling equipment contaminated with diesel engine oil. Workers are expected to wear appropriate personal protective equipment (PPE) to minimize dermal exposure. Overall, exposure to the notified polymer

will be low, given the low concentration (up to 0.6%) of notified polymer in the finished diesel engine oils and the measures in place to lower exposure.

At mechanical workshops, professional users such as mechanics may experience dermal or ocular exposure to the final product containing the notified polymer at up to 0.6%, when adding the diesel engine oil to the automobile and other machinery. The potential for dermal and ocular exposure is reduced if workers wear appropriate PPE such as gloves, long sleeve clothing and eye protection.

6.1.2. Public Exposure

The notified polymer will be used as a dispersant in diesel engine oil. Therefore, once engine oil containing the notified polymer is added to the engine, the general public will not be exposed to the notified polymer in the engine oil. Furthermore, exposure to the general public during the addition of engine oil is also expected to be minimal as most diesel engine oils are added and/or replaced by certified mechanics. However, DIY users may experience inadvertent dermal and ocular exposure to final products containing up to 0.6% of the notified polymer when adding and/or replacing engine oil of their vehicles.

Overall, public exposure is expected to be limited due to the infrequent use and the low concentration of the notified polymer in finished diesel engine oil.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (40% purity)	LD50 > 2000 mg/kg bw; low toxicity
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), low levels of low molecular weight species, and also high n-octanol value (log P_{ow} >9.4) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited.

Acute toxicity.

The acute oral toxicity of the notified polymer was studied in rats in accordance with OECD TG 420 (Harlan 2010c). The test material containing the notified polymer at 40% purity was administered to 5 animals at a dose level of 2000 mg/kg bw. No mortalities, signs of systemic toxicity or abnormalities in body weight gain or necropsy findings were observed. It was concluded that the test material containing the notified polymer was of low acute oral toxicity (LD50 > 2000 mg/kg bw). It was not clear from the study report whether the dosage had been adjusted for purity.

Mutagenicity.

The mutagenicity of the notified polymer was examined using a reverse mutation assay (Ames test, plate incorporation method) in accordance with OECD TG 471 (Harlan 2010d). The notified polymer (purity of 40% with 60% mineral oil) was tested using tetrahydrofuran as the vehicle. Formulated concentrations were adjusted to allow for the purity of the notified polymer. It was ensured that the levels of tetrahydrofuran present at dosing were below the levels known to be toxic to bacterial cells. The notified polymer was tested at doses up to 5000 μg/plate. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose level, either with or without the presence of metabolic activation. Thus the notified polymer was concluded to be non-mutagenic under the conditions of the test.

Health hazard classification

Based on the data provided, the notified polymer is not 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 studies, was of low acute oral toxicity in rats at 40% purity and is not expected to be genotoxic. Furthermore, based on its high molecular weight and high n-octanol value, the

potential of the notified polymer to cross the GI tract by passive diffusion or to be dermally absorbed after exposure are 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 4% concentration during reformulation and change/addition of engine oil in vehicles manufacturing or mechanical workshops. However, the level of exposure is not expected to be significant considering the relatively low concentration of the notified polymer in these products (less than 4%) and the control measures in place, including engineering controls, automated processes and the use of PPE. Therefore, the risk to the health of workers associated with use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The general public is not expected to be exposed to engine oils containing the notified polymer (up to 0.6% concentration), as diesel engine oils are typically added and/or replaced by mechanics. Some inadvertent exposure of DIY users to the notified polymer may occur. However, the risk is not considered to be unreasonable in light of low concentrations of the notified polymer (up to 0.6%) present in finished diesel engine oils and the low frequency of exposure. Thus the notified polymer does not pose an unreasonable risk to the health of the general public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be manufactured and blended overseas into additive packages, and will be imported into Australia in drums and isotainers for use as a dispersant in diesel engine oil. Further blending with other ingredients may be required at customer's blending facilities.

At the blending facilities (if it is applicable), release during the highly automated blending process is not expected. The equipment used will typically be cleaned with oil, with these washings used in the formulation of the next batch or another oil blend. In these situations release would occur through accidental spills, which would be recycled or collected for proper disposal and most likely landfilled. Any of the notified polymer remaining in the import containers, expected to be < 1% of the contents, would be washed out and recycled or collected for proper disposal and most likely landfilled.

RELEASE OF CHEMICAL FROM USE

Some minor, diffuse exposure will result from spills during addition to and removal of oil from machines. For vehicle applications, the notifier estimates that 90% of oil changes take place in specialised automotive service centres, where release of the notified polymer from professional activities should be disposed of appropriately. The remaining 10% of oil changes will be performed by do-it-yourself (DIY) users. Of the diesel engine oil containing the notified polymer disposed of by DIY users, approximately 20% will be collected for recycling, 25% will be buried or disposed of in landfill, 5% (i.e. 0.5% of the total import volume) may be disposed of inappropriately into storm water drains and the remaining 50% will be used in treating fence posts, killing grass and weeds or disposed of in other ways (Snow, 1997).

RELEASE OF CHEMICAL FROM DISPOSAL

Iso-containers and drums are expected to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies will typically be passed to an on site waste treatment facility and any waste sludge may be sent to landfill.

7.1.2. Environmental Fate

No environmental fate data for the notified polymer were submitted. The notified polymer is likely to be mainly disposed of by thermal decomposition as part of the process to recover the calorific value of used lubricants. Smaller amounts may be consigned to landfill, or disposed of inappropriately to land or stormwater. Thermal decomposition would destroy the notified polymer, while disposal to land or landfill would result in its immobilisation because of the strong sorption to soil organic carbon. If disposed of to water, the notified

polymer is likely to spread across the surface of the water and sorb to suspended solids and sediment. Either in landfill or through thermal decomposition, the notified polymer will finally be decomposed into water and oxides of carbon and nitrogen. The notified polymer has a low solubility in water and a high molecular weight, and therefore, is not expected to be bioavailable or bioaccumulative to aquatic organisms.

7.1.3. Predicted Environmental Concentration (PEC)

The percentage of the imported quantity of notified polymer inappropriately disposed to stormwater drains is estimated be 0.5%. That is, 10% (fraction collected by DIY users) × 5% (fraction disposed to stormwater). A worst case PEC can be calculated if it is assumed that 0.5% of the notified polymer (maximum 500 kg) is released into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 500 kg and the annual volume of water drained from this region estimated to be 250×10^6 m^3, the resultant PEC is approximately 2 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple urban areas. Moreover, the notified polymer will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. The notified polymer contains functionality which, when ionised, has the potential to cause adverse effects to aquatic biota. However, the extent of ionisation is not expected to be significant at environmental pH. Furthermore, the release to the aquatic compartment is expected to be very low.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as ecotoxicologically significant concentrations are not expected to be reached based on its assessed use pattern as a component of diesel engine oils. Furthermore, the aquatic PEC estimated for the notified polymer is an upper limit due to sorption of the notified polymer to sludge and sediment. The notified polymer is not expected to be bioavailable nor bioaccumulative to aquatic organisms. Therefore, the risk of the notified polymer to the environment is not expected to be unreasonable based on its assessed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is not 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 unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable 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.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills 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 polymer has changed from diesel engine oil additive, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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 polymer 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

Vapour Pressure 7.8×10^{-4} Pa at 25°C

Method	EC No 440/2008
Remarks	The vapour pressure was determined using a vapour pressure balance according to the guidelines above. A sequence of runs was started after the test substance had been under vacuum for approximately 96.5 hours. Temperature and pressure readings were taken between 90 and 100°C with a one hour dwell at 90°C between runs.
Test Facility	Harlan Laboratories Ltd. (2010a)

Water Solubility $\leq 75.1 \times 10^{-3}$g/L at 20°C (pH 2, 7 and 9)

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks	Flask Method. Three samples of test substance (approximately 10 g each) were added to three flasks of 1000 mL double distilled water and solution was adjusted to pH = 2. Each flask was shaken at 20°C for 24 hours. The method was repeated with samples at pH 7 and 9. All samples contained excess undissolved test substance floating on the surface and stuck to the sides of the flasks. The samples were subsequently centrifuged at 2000 rpm for 30 min and were all found to be free from undissolved test substance. The concentration of test substance was determined using GPC.
Test Facility	Harlan Laboratories Ltd. (2010b)

Partition Coefficient (n-octanol/water) log Kow > 9.4

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. The partition coefficient was determined by extrapolation from a calibration curve constructed from six known standards (log Kow range 0.3 to 9.4) in accordance with the guidelines above. The test was conducted at approximately neutral pH and the test substance was reported to be non-ionised. The retention time of the test substance exceeded that of the standard with highest log Kow, and hence the test substance was reported to have a higher log Kow than the maximum log Kow measured.
Test Facility	Harlan Laboratories Ltd. (2010b)

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