File No.: LTD/2104

November 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Z-194

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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 Energy.

This Public Report is 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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SUMMARY

The following details will be published in the NICNAS Chemical Gazette:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2104	Lubrizol International, Inc.	Z-194	ND*	≤ 15 tonnes per annum	A component of automotive fluids

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment

Under the conditions of the occupational settings described (PPE for end-use), 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

Based on the low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation:
 - Enclosed/automated processes
- A person conducting a business or undertaking at a workplace should implement the following safe work
 practices to minimise occupational exposure during handling of the notified polymer as introduced,
 during reformulation and end use:
 - Avoid contact with skin and eyes
- A person conducting a business or undertaking at a workplace should ensure that the following personal
 protective equipment is used by workers to minimise occupational exposure to the notified polymer as
 introduced, and during reformulation:
 - Impervious gloves
 - Protective clothing
 - Safety glasses or goggles
 - Respiratory protection if inhalation exposure may occur

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

A copy of the SDS should be easily accessible to employees.

• If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency procedures

• Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

• Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000 g/mol;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of automotive fluids, or is likely to change significantly;
 - the amount of polymer being introduced has increased, 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.

Safety Data Sheet

The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Lubrizol International Inc. (ABN 52 073 495 603)

28 River Street

SILVERWATER NSW 2128

NOTIFICATION CATEGORY

Limited (reduced fee notification): Synthetic polymer with $Mn \ge 1,000$ g/mol – Similar to a chemical that has been previously assessed by NICNAS (LTD/1449).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are varied for all physico-chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-194

MOLECULAR WEIGHT

Number average molecular weight (Mn) is > 10,000 g/mol.

ANALYTICAL DATA

Reference FTIR, NMR, TGA, and GPC spectra were provided.

3. COMPOSITION

Degree of Purity > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Viscous light amber liquid*

Property	Value	Data Source/Justification
Pour Point*	44 °C	Analogue data
Boiling Point*	Decomposes at > 314 °C at 100.8 kPa	Analogue data
Density*	$927 \pm 5 \text{ kg/m}^3 \text{ at } 26.5 \pm 2 ^{\circ}\text{C}$	Analogue data
Vapour Pressure*	$1.6 \times 10^{-7} \text{ kPa at } 25 ^{\circ}\text{C}$	Analogue data
Water Solubility*	10.3 mg/L	Analogue data
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups that are unlikely to significantly hydrolyse due to low water solubility
Partition Coefficient* (n-octanol/water)	log Pow > 9.4	Analogue data

Property	Value	Data Source/Justification
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sewage sludge based on its high molecular weight and high partition coefficient
Dissociation Constant	Not determined	Contains functional groups that are expected to be ionised in the environmental pH range (4–9)
Flash Point*	162 ± 2 °C at 101.3 kPa	Analogue data
Autoignition Temperature*	352 ± 5 °C	Analogue data
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

^{*} Analogue data

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical Hazard Classification

Based on the submitted physico-chemical data depicted in the above table for the analogue, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

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. It will be imported at a concentration of < 50% for reformulation.

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

Year	1	2	3	4	5
Tonnes	1-10	1-10	1-10	5-15	5-15

TRANSPORTATION AND PACKAGING

The imported product containing the notified polymer will be in sealed 55 gallon drums and may be repackaged in the same drums or in smaller containers for do-it-yourself (DIY) use. Transportation will be by road or railway.

Use

The notified polymer will be used as a viscosity modifier for automotive fluids and will be present in the finished products at $\leq 0.025\%$ concentration.

OPERATION DESCRIPTION

Reformulation

At the reformulation sites, the imported product containing the notified polymer at < 50% concentration will be pumped from the containers into mixing tanks where it will be blended with other additives into finished automotive fluid products. These products will then typically be pumped into drums and smaller aftermarket containers. The blending operations are expected to be carried out in automated and closed systems with appropriate engineering controls such as a catch basin and drip pans to collect any spilled materials and local exhaust ventilation to capture any fumes.

End-use

Finished automotive fluid products reformulated in Australia containing the notified polymer at $\leq 0.025\%$ concentration will be added to vehicles by mechanics in mechanical workshops. A portion may also be used by do-it-yourself (DIY) consumers who replace engine oils in their vehicles.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport	4-6	4-6
Operator	8	20-30

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified polymer only in the event of accidental rupture of the packaging.

Reformulation

Plant operators may experience dermal and ocular exposure to the notified polymer at concentrations < 50% when connecting and disconnecting pump lines to storage tanks or blending vessels and during sample testing. The blending facilities are expected to be largely automatic, with enclosed systems and ventilation. Dermal exposure of workers may occur when cleaning up spills or leaks and during maintenance of the blending equipment. The use of PPE such as coveralls, goggles, impervious gloves and respiratory protection by the workers as anticipated by the notifier (as recommended on the SDS), and a high degree of automation will minimise exposure to the notified polymer during reformulation.

Transfer of the finished automotive fluids containing the notified polymer at < 0.025% concentration to packaging will mainly be performed by automated processes; hence, exposure to workers is expected to be minimal.

End use

Workers at vehicle manufacturers, mechanical workshops, or professional users may be exposed to oils containing the notified polymer at $\leq 0.025\%$ concentration. The finished oils will be added to engines, or transmission systems using automated systems or by manual transfer. According to the notifier, workers are expected to wear PPE such as gloves and safety glasses to minimise exposure.

6.1.2. Public Exposure

Dermal and or ocular exposure to the notified polymer at $\leq 0.025\%$ concentration may occur to DIY users when topping up or changing engine oils. Given engine oil is topped up or changed infrequently and the low concentration of the notified polymer in the finished products, public exposure to the notified polymer is expected to be very low.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. However, the results from a similar chemical that was previously assessed (LTD/1449) are summarised below, and used as analogue information for the notified polymer:

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, Metabolism and Distribution

The notified polymer is not expected to be absorbed across biological membranes given its high molecular weight (> 10,000 g/mol.), low water solubility (10.3 mg/L for an analogue), and high partition coefficient (log Pow > 9.4 for an analogue).

Acute Toxicity

The analogue polymer (\sim 80% in diluent oil) was found to be of low acute oral toxicity in a study in rats conducted according to OECD TG 420. No mortalities or adverse effects were observed during the study. The acute oral LD50 was determined to be > 2000 mg/kg bw.

Mutagenicity

The analogue polymer (~80% in diluent oil) was found not to be mutagenic when tested at up to 5000 μg/plate in a bacterial reverse mutation test (OECD TG 471) conducted in the presence and absence of metabolic activation in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2uvrA⁻.

Health Hazard Classification

As no toxicity data were provided on the notified polymer and only limited data are available on the analogue polymer, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is expected to be of low systemic toxicity due to the predicted low bioavailability. An analogous polymer was shown to be of low acute oral toxicity and was not mutagenic in bacteria.

During reformulation, workers may be exposed to the notified polymer at up to 50% concentration. The notifier states that engineering controls such as enclosed and automated processes and local ventilation will be implemented where possible and appropriate PPE (coveralls, impervious gloves, eye protection and respiratory protection) will be used to limit exposure to workers during reformulation.

During end use, professional workers may be exposed to the notified polymer at < 0.025% concentration when manually decanting the automotive fluids. According to the notifier, appropriate PPE (coveralls, impervious gloves and eye protection) will be used by workers to limit exposure.

Therefore, under the occupational settings described and with the stated controls in place, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Incidental dermal and ocular exposure to the notified polymer may occur to members of the public (DIY users) when adding automotive fluids containing the notified polymer at < 0.025% concentration to vehicles. It is not known whether DIY users would use PPE during this process. However due to the very low concentration of the notified polymer in end use products adverse effects from exposure to it are not expected. In addition, the frequency and extent of exposure are expected to be less than that of professional workers, and the risk to the public from use of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer is not manufactured in Australia and will only be imported for reformulation into automotive fluids such as motor oils and Automatic Transmission Fluids (ATF). Reformulation is expected to occur in processes involving automatic blending operations in closed systems, followed by automatic filling of the reformulated products into end-use containers. Any waste generated from the reformulation process is expected to be disposed of by an approved waste management facility. Accidental spills of the products containing the notified polymer during import, transport, reformulation or storage are expected to be collected for recycling or disposal of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The finished engine oil containing the notified polymer will be available to motor mechanics and public (DIY users). Motor mechanics will pump the finished oil containing the notified polymer from the 208 L drums into the vehicle oil reservoir. DIY users will manually transfer the finished oil containing the notified polymer from the smaller containers into the vehicle oil reservoir. Both motor mechanics and DIY users will manually drain spent oil containing the notified polymer from the engine during servicing.

In a recent Australian survey it was found that only 4% of households disposed of motor oil and approximately 70% of this motor oil was correctly disposed (Aither, 2013). Some vehicle lubricating oil is consumed during use but the amount consumed is highly variable (0 - 99%) depending on the type and use of oil. Although there is some uncertainty, it may be estimated based on this data that approximately 1% (0.04×0.3) of all motor oil sold could be incorrectly disposed by DIY users. Accordingly, about 1% of the notified polymer in used oil may be disposed of incorrectly. Release during use may arise from drips during manual oil addition to tanks, but this is expected to be minimal. For ATF, the trend for these types of transmissions is "fill for life", with no scheduled servicing (drain and refill). Therefore, the amount of transmission fluid likely to be disposed of by DIY users will be less than that for motor oil.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer are expected to remain in the empty drums and containers. Empty drums are expected to be cleaned and recycled, with the residual oil being collected and disposed of by approved waste management contractors, in accordance with local government regulations. DIY containers are expected to be either recycled or disposed of to landfill. Other than, small amounts of oil incorrectly disposed of, the used oil containing the notified polymer is expected to be collected and recycled, re-refined or disposed of by approved waste management contractors, in accordance with local government regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Most of the notified polymer will be recycled, refined or disposed of by approved waste management contractors. During refining, it is likely that the notified polymer will degrade into simpler compounds. A small amount of the total import volume may be thermally decomposed during engine operation or through re-use in low-grade fuels as an energy source. Small amounts may also be consigned to landfill, or disposed of inappropriately to land or stormwater. Disposal to land or landfill would result in its immobilisation because of the expected strong sorption to soil organic carbon. If disposed of to water, the notified polymer is likely to adsorb to suspended solids and sediment. The notified polymer will eventually be degraded by biotic and abiotic processes in landfill or thermally decomposed to form water and oxides of carbon, nitrogen. The notified polymer is not expected to bioaccumulate due to its high molecular weight.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated. It is expected that approximately 1% (150kg per annum) may be incorrectly disposed of. However, this is expected to be dispersed and not all of this volume will reach waterways. Therefore, the concentration in the aquatic environment is expected to be limited.

7.2. Environmental Effects Assessment

No ecotoxicity studies were provided for the notified polymer. The ecotoxicological investigation provided was conducted on a similar chemical, which was previously assessed (LTD/1449). An additional endpoint for daphnia toxicity was also provided which was derived from the SDS for the notified polymer.

Endpoint	Result	Assessment Conclusion
Daphnia Toxicity	EC50 > 10,000 mg/L	Not expected to be harmful to daphnia (SDS)
Algal Toxicity*	EC50 > 100 mg/L	Not harmful to algae at the limit of solubility

^{*} Analogue data

Based on the above ecotoxicological endpoints, the notified polymer is not expected to be harmful to aquatic organisms. Therefore, the notified polymer is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) for acute and chronic toxicities (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated, as the notified polymer is not expected to be harmful to aquatic organisms up to its limit of water solubility.

7.3. Environmental Risk Assessment

A risk quotient was not calculated due to the expected low environmental release of the notified polymer and the expected lack of harm to aquatic organisms up to its limit of water solubility.

Based on the low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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