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AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Z-193

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals Act 2019 (the IC Act) and Industrial Chemicals (General) Rules 2019 (the IC Rules) by following the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act) and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) 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 Agriculture, Water and the Environment.

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SUMMARY

The following details will be published on the AICIS website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2155	Lubrizol International Inc.	Z-193	ND*	< 10 tonnes per annum	Additive in transmission fluids

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

As only limited toxicity data were provided, the assessed polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment

Under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

When use in the proposed manner, the assessed polymer is not considered to pose an unacceptable risk to public health

Environmental Risk Assessment

On the basis of the reported use pattern, the assessed 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 assessed polymer during reformulation:
 - Enclosed/automated processes
 - Adequate general ventilation
- 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 assessed polymer during
 reformulation and final use:
 - Avoid contact with skin and eyes
- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the assessed 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 assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information

This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC Act the applicant of the assessed polymer has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 days by the applicant or other introducers if:

- the function or use of the assessed polymer has changed from an additive in automatic transmission fluids or is likely to change significantly;
- the amount of assessed polymer being introduced has increased, or is likely to increase, significantly;
- the assessed polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the assessed

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet

The SDS of the assessed polymer provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)

Lubrizol International Inc. (ABN: 52073495603)

28 River Street, P.O. Box 6445, SILVERWATER, NSW, 2128

APPLICATION CATEGORY

Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)

Data items and details taken to be protected information include: Chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES) Schedule data requirements are not varied.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)

None

APPLICATION IN OTHER COUNTRIES

Canada (1998)

China (2013)

Korea (Republic of) (2014, 2016)

Taiwan (2015)

United States of America (2020)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-193

MOLECULAR WEIGHT

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

3. COMPOSITION

ADDITIVES/ADJUVANTS

None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Under normal conditions of use, hazardous decomposition products are not expected to be produced.

DEGRADATION PRODUCTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Melting Point	<-20 °C	Measured
Boiling Point	400 °C at 101.3 kPa	Measured
Density	$1.17 \times 10^3 \text{ kg/m}^3 \text{ at } 20 \pm 0.5 ^{\circ}\text{C}$	Measured
Vapour Pressure	3.85 x 10 ⁻² kPa at 25 °C	Measured
Water Solubility	Insoluble	Measured

Property	Value	Data Source/Justification
Hydrolysis as a Function of	Negligible	Insoluble in water
pH		
Partition Coefficient	$\log Pow > 10.0$	Measured
(n-octanol/water)		
Adsorption/Desorption	$\log \text{Koc} > 5.6$	Measured
Dissociation Constant	Could not be determined	Insoluble in water
Flash Point	115 ± 2 °C at 101.3 kPa	Measured
Flammability	Not determined	
Autoignition Temperature	402 °C	Measured
Explosive Properties	Negative	Contains no functional groups that would
		imply explosive properties
Oxidising Properties	Negative	Contains no functional groups that would
	_	imply oxidising properties

DISCUSSION OF PROPERTIES

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

Reactivity

The assessed 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, the assessed polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL OVER NEXT 5 YEARS

The assessed polymer will be imported into Australia as part of a finished fluid at < 0.01% concentration or as part of an additive package at < 0.05% concentration that will be blended into finished fluids.

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

Year	1	2	3	4	5
Tonnes	< 1 MT	< 1 MT	< 10 MT	< 10 MT	< 10 MT

PORT OF ENTRY

Perth, Brisbane and Melbourne

IDENTITY OF RECIPIENT

Lubrizol International Inc.

28 River Street

Silverwater NSW 2128

TRANSPORTATION AND PACKAGING

The assessed polymer will be imported into Australia in either 330 gallon containers or iso-containers with smaller quantities being transported in 55 gallon drums. The assessed polymer is expected to be transported from the dockside to warehouses primarily via truck, but rail transport may also be possible. The assessed polymer will then be stored until required for reformulation.

USE

The assessed polymer will be used as an additive in transmission fluids.

OPERATION DESCRIPTION

Reformulation and packaging

At the customer's blending facility, the additive package containing the assessed polymer will be manually transferred from its transportation container to a mixing tank where it will be mixed with other automatic transmission fluids. The mixing process is expected to be fully automated enclosed within a blend facility that is

expected to be well ventilated. After blending, the fluid will be packaged into containers of the customer's choice. Packaging equipment is expected to be automated and housed within or nearby the blending facility.

End use

End use products containing the assessed polymer at < 0.01% concentration will be used by equipment manufacturers and industry professionals who are trained to handle lubricants for vehicles. These products are likely to be poured manually from containers into the inlet valves of vehicles.

Products containing the assessed polymer will also be available to do-it-yourself (DIY) users who change the lubricants in their vehicles. However, this is not expected to be a common use.

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)
Reformulation	1-3	3-4
Packaging	2-4	1-3
Distribution	0-2	100-225

EXPOSURE DETAILS

Storage and distribution

Distribution workers involved in transport and warehouse storage are expected to only come into contact with the assessed polymer (at < 0.1% concentration) in the unlikely event of an accident.

Reformulation and packaging

Dermal and ocular exposure of workers to the assessed polymer may occur due to drips, spills and splashes during charging of mixer, blending, sampling and filling and maintenance processes. Exposure to the assessed polymer at other times is expected to be negligible given the formulation process will be largely enclosed and automated. Exposure will be further limited by the workers using PPE such as coveralls, goggles and impervious gloves. Inhalation exposure of the assessed polymer is not expected due to the low vapour pressure of the assessed polymer.

End-use

Dermal and ocular exposure of workers to the assessed polymer (at < 0.01% concentration) may occur when manufacturers and industry professionals involved in industries that involve changing of vehicle lubricants. Given the low vapour pressure of the assessed polymer, inhalation exposure is not expected. Dermal and ocular exposure to workers would be mitigated through the use of PPE.

6.1.2. Public Exposure

Products containing the assessed polymer will be used in primarily in industrial settings and will not be made widely available to the public. On rare occasions, products containing the assessed polymer may be handled by DIY users who change the lubricants in their vehicles. Dermal and ocular exposure to the assessed polymer at < 0.01% concentration may occur during changing of vehicle lubricant. However, considering that the vehicle lubricant is changed occasionally and this activity is only for a short duration, exposure is expected to be limited.

6.2. Human Health Effects Assessment

The results from an acute oral toxicity study conducted on the assessed polymer are summarised in the following table. For details of the study, refer to Appendix B.

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

Acute Toxicity

Based on a study conducted in rats, the assessed polymer is of low acute oral toxicity.

Health Hazard Classification

As only limited toxicity data were provided, the assessed 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

Based on the limited toxicity data provided, the assessed polymer is expected to be of low acute oral toxicity. The assessed polymer is not expected to be absorbed across biological membranes, given its high molecular weight (> 10,000 g/mol), water insolubility, and high partition coefficient (log Pow > 10.0). Furthermore, the assessed polymer contains no detectable low molecular weight species (< 1,000 g/mol) and based on the available information, systemic toxicity effects are not expected from the use of the assessed polymer. However, local hazards about the assessed polymer cannot be ruled out.

6.3.1. Occupational Health and Safety

During reformulation and packaging, workers may be exposed to the assessed polymer at < 0.1% concentration. Given that the reformulation processes will be largely enclosed and automated and that the workers will use PPE such as coveralls, goggles, and impervious gloves, dermal and ocular exposure to the assessed polymer is expected to be negligible. Given the low vapour pressure of the assessed polymer, inhalation exposure is not expected.

During end-use, manufacturers and industry professionals may be exposed to the assessed polymer (at < 0.01% concentration) during changing of vehicle lubricants. While dermal and ocular exposure to workers would be mitigated through the use of PPE, inhalation exposure is not expected as the vapour pressure of the assessed polymer is low. Therefore, under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Products containing the assessed polymer will be used in primarily in industrial settings and will not be made widely available to the public. Dermal and ocular exposure to the assessed polymer (at < 0.01% concentration) may occur to DIY users who, on rare occasions, change their own vehicle lubricants. While it is not known whether DIY users would use PPE during this process, considering the very low concentration of the assessed polymer in end use products and the infrequent use, adverse effects from exposure to the assessed polymer are not expected

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed polymer will be imported into Australia as part of an additive package for reformulation into automatic transmission fluids (ATFs). The blending facility is expected to be fully automated, with minimal losses. Waste generated from cleaning of equipment is also expected to be minimal as similar materials and products are blended in the same equipment. Any waste generated from reformulation process and spills containing the assessed polymer are expected to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The ATFs containing the assessed polymer will mainly be used by equipment manufacturers and industry professionals who are trained to handle lubricants for vehicles. Used transmission fluids is expected to be collected by authorised contractors for recycling, re-refining or disposal of in accordance with local government regulations. As a result, no release to aquatic environment is expected from these activities.

The ATFs containing the assessed polymer could also be used by the public to a limited extent. Release during use may arise from drips while adding the fluids to the fluid tank manually, but it is expected to be minimal. Used fluids may also be disposed of by DIY users. In a recent Australian survey it was found that only 4% of households disposed of motor oil and that approximately 70% was correctly disposed of (Aither, 2013). Some vehicle lubricating oil is consumed during use but this is highly variable (between 0 and 99%), depending on the type of oil and its use. Although there is some uncertainty, based on this data, it may be estimated that \sim 1% (0.04 \times 0.3)

of all motor oil sold is incorrectly disposed of by DIY users. For ATF applications, the trend for these types of transmissions is "fill for life", with no scheduled servicing (drain and refill). Therefore the amount of transmission fluids likely to be disposed of by DIY users will be less than that for motor oil. Accordingly less than 1% of the assessed polymer present in ATFs is expected to be disposed of incorrectly. The assessed polymer contained in ATFs is expected to be collected at the end of their useful life and recycled, re-refined or disposed of, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers containing residues of the assessed polymer are expected to be reused or disposed of, in accordance with local government regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Any used or waste fluids containing the assessed polymer is expected to be recycled, re-refined or disposed of by authorised waste management facilities. It is likely that the assessed polymer will be degraded into simpler compounds during refining. The assessed polymer in the environment is expected to eventually degrade into water and oxides of carbon and silicon and simple fluorine compounds via biotic and abiotic pathways.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the assessed polymer to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the assessed polymer are summarised in the table below. Details of the study can be found in Appendix C.

Result	Assessment Conclusion
•	Not harmful to algae
	> 100 mg/L WAF* 00 mg/L WAF*

^{*}WAF: Water Accommodated Fraction

The above algal toxicity results show the assessed polymer is not harmful to algae. Therefore, the assessed polymer is not classified according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration (PNEC)

The PNEC was not calculated as the assessed polymer is not expected to be harmful to aquatic organisms.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated as the assessed polymer is not expected to be harmful to aquatic organisms and release of the assessed polymer to the aquatic environment will be limited based on its reported use pattern. On the basis of the low hazard and the reported use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point < -20 °C

Method OECD TG 102 Melting Point/Melting Range

EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature

Remarks Determined using the crystallising point method

Test Facility Covance (2020a)

Boiling Point No boiling point up to 400°C at 102 kPa

Method OECD TG 103 Boiling Point

EC Council Regulation No 440/2008 A.2 Boiling Temperature

Remarks Determined by differential scanning calorimetry (DSC)

Test Facility Covance (2020a)

Density $1.17 \times 10^3 \text{ kg/m}^3 \text{ at } 20.0 \pm 0.5 \text{ °C}$

Method OECD TG 109 Density of Liquids and Solids

EC Council Regulation No 440/2008 A.3 Relative Density

Remarks Determined using the pycnometer method

Test Facility Covance (2020a)

Vapour Pressure 3.85 x 10⁻² kPa at 25 °C

Method OECD TG 104 Vapour Pressure

EC Council Regulation No 440/2008 A.4 Vapour Pressure

Remarks Determined using vapour pressure balance

Test Facility Covance (2020d)

Water Solubility Essentially insoluble

Method OECD TG 120 Water Solubility

EC Council Regulation No 440/2008 A.20 Solution/Extraction Behaviour of Polymers in

Water

Remarks Flask Method Test Facility Covance (2020a)

Partition Coefficient $\log Pow > 10.0$

(n-octanol/water)

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

EC Council Regulation No 440/2008 A.8 Partition Coefficient

Remarks HPLC Method Test Facility Covance (2020a)

Adsorption/Desorption $\log \text{Koc} > 5.6$

Method OECD TG 121 Estimation of Adsorption Coefficient

Remarks HPLC method Test Facility Covance (2020b)

Flash Point $115 \pm 2 \, ^{\circ}\text{C}$

Method EC Council Regulation No 440/2008 A.9 Flash Point

Remarks Determined using flash point tester

Test Facility Covance (2020f)

Auto-Ignition Temperature 402 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)

Remarks Determined using a carbolite flask heater

Test Facility Covance (2020f)

Explosive Properties

Method EC Council Regulation No 440/2008 A.14 Explosive Properties

Remarks Based on the chemical structure of the test item, the result for explosive properties has been

predicted negative

Test Facility Covance (2020f)

Oxidizing Properties

Method EC Council Regulation No 440/2008 A.21 Oxidising Properties (Liquids)

Remarks Based on the chemical structure of the test item, the result for oxidising properties has been

predicted negative

Test Facility Covance (2020f)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat, Fixed Dose

TEST SUBSTANCE Assessed polymer

METHOD OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure

EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed

dose method

Species/Strain Rat WIST albino

Vehicle Corn oil

Remarks – Method A separate sighting study and main study were performed for the assessed

polymer. In the sighting study, one female was dosed with 2,000 mg/kg

bw of the assessed polymer.

Based on the results from the sighting study, a dose of 2,000 mg/kg bw

was chosen for the main study.

No major deviations from the test guideline were reported.

The testing laboratory was GLP compliant.

RESULTS

Group	Number and Sex of Animals	Dose (mg/kg bw)	Mortality	
1	4F	2000	0/4	
LD50	> 2000 mg/kg bw	f 4: - 4 - 4 4 4 4 4 - 1	1 4 4 1 4 1	
Signs of Toxicity	<u> </u>	f reaction to treatment through	•	
Effects in Organs	examination	were noted in any anim	•	
Remarks – Results	mg/kg, on Days 8-	A low body weight gain was seen in one animal only, dosed at 2000 mg/kg, on Days 8-15. All other animals were considered to have achieved satisfactory body weight gains throughout the study.		
Conclusion	The assessed polyi	ner is of low acute toxicity vi	a the oral route.	
TEST FACILITY	Covance (2020e)			

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Algal Growth Inhibition Test

TEST SUBSTANCE Assessed polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test

EC Council Regulation No 440/2008 C.3 Algal Inhibition Test

Species Raphidocelis subcapitata (formerly known as Pseudokirchneriella

subcapitata)

Exposure Period 72 hours
Nominal Concentration 100 mg/L
Auxiliary Solvent None
Water Hardness Not provided

Analytical Monitoring Total Organic Carbon (TOC)

Remarks – Method

A limit test was run based on results of a preliminary range-finding test

with no major deviations from the test guidelines. Due to the low aqueous solubility and complex nature of the test item, the test medium was prepared as a Water Accommodated Fraction (WAF) of the test item. TOC analysis of the test preparations containing no algal cells was performed at 0 and 72 hours. A reference test with potassium dichromate was run as

part of a bi-annual quality assurance program.

RESULTS

Bioma	ISS	Grow	th
EyL_{50}	NOEL	ErL_{50}	NOEL
(mg/L WAF at 72 h)	(mg/L WAF)	(mg/L WAF at 72 h)	(mg/L WAF)
> 100	100	> 100	100

Remarks - Results

All validity criteria for the test were satisfied, the biomass factor increased by 284 times. The mean coefficient of variation for section-by-section growth rates was 10%. The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 1%. The 72 h ErC50 for algae exposed to potassium dichromate was 1.3 mg/L which was within the range of expected responses. Analysis of the 100 mg/L loading rate WAF at 0 hours gave a measured carbon concentration of 1.4 mg/L, whilst analysis at 72 hours gave a measured carbon concentration of 0.68 mg/L.

CONCLUSION The test substance is not harmful to algae.

TEST FACILITY Covance (2020c)

BIBLIOGRAPHY

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- Covance (2020a) [Assessed Polymer]: Determination of General Physico-chemical Properties (Study No. FS47SP, February 2020). Covance CRS Research Limited, Derbyshire, UK (Unpublished report submitted by the applicant).
- Covance (2020b) [Assessed Polymer]: Determination of Adsorption Coefficient (Study No. QK94TV, February 2020). Covance CRS Research Limited, Derbyshire, UK (Unpublished report submitted by the applicant). Could not find this in the TRIM
- Covance (2020c) [Assessed Polymer]: Algal Growth Inhibition Test (Study No. PJ09KR, May 2020). Covance CRS Research Limited, Derbyshire, UK (Unpublished report submitted by the applicant).
- Covance (2020d) [Assessed Polymer]: Determination of Vapour Pressure (Study No. WK76RN, January, 2020). Covance CRS Research Limited, Derbyshire, UK (Unpublished report submitted by the applicant).
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- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), see http://www.unece.org/trans/danger/publi/ghs/ghs rev03/03files e.html