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AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Dispersant in G001790M3

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 human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1239	Lubrizol International, Inc. (Australia) Volkswagen Group Australia Pty Ltd	Dispersant in G001790M3	ND*	≤ 10 tonnes per annum	Component of fuel additives and industrial printing inks

*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), 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 used in the proposed manner, the assessed polymer is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the assessed use pattern and the maximum import volume, the assessed polymer is not considered to pose an unreasonable risk to the aquatic environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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 final use:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace with fuel additives containing the assessed polymer should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the assessed polymer during final use:
  - Impervious gloves
  - Safety glasses or goggles
  - Protective clothing

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the assessed polymer and during routine maintenance and repairs.

  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 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.

Transport and Packaging

- Although the assessed polymer itself is not flammable certain products containing the polymer are flammable liquids, and introducers of the polymer should consider their obligations under Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code) (NTC, 2018).

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 introducer of the assessed chemical 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 working days by the applicant or other introducers if:

- the polymer has a number-average molecular weight of less than 1000 g/mol;
- the function or use of the polymer has changed from components of fuel additives and industrial printing inks, 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 human health, or the environment.

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

Safety Data Sheet
The SDS of products containing the assessed polymer provided by the applicant were 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. (Australia) (ABN: 52 073 495 603)
28 River Street
SILVERWATER NSW 2128

Volkswagen Group Australia Pty Ltd (ABN: 14 093 117 876)
24 Muir Road
CHULLORA NSW 2190

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, other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for all physio-chemical properties.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dispersant in G001790M3

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference NMR, MALDI MS, IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>96%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark brown sticky solid

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point	Not determined	Imported in solution
Boiling Point	Not determined	Expected to decompose prior to boiling
Density*	882 kg/m3 at 15.6 °C	SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight
Water Solubility	Not determined	Expected to be dispersible in water
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities
Partition Coefficient		

Property	*Value*	*Data Source/Justification*
(n-octanol/water)	Not determined	Expected to exhibit surfactant properties
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on polymer structure.
Dissociation Constant	Not determined	Expected to be insoluble in water
Particle Size	Not determined	Imported in solution
Flash Point	Not determined	Imported in flammable solvent
Autoignition Temperature	Not determined	Imported in flammable solvent
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* For the assessed polymer at < 55% in solvent

DISCUSSION OF PROPERTIES

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),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed polymer will be introduced as a component of finished fuel additive products at ≤ 30% concentration and as a component of industrial printing inks at 1-10% concentration.

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

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

PORT OF ENTRY
Throughout Australia

TRANSPORTATION AND PACKAGING
Finished fuel additive products will be imported in 150 ml plastic bottles, and inks will be supplied in cartridges, 1 L bottles or foil bags.

USE
The assessed polymer will be used as a dispersant in finished additives for diesel fuel at ≤ 30% concentration by professional workers and DIY users. It will also be used as a dispersant at 1-10% concentration in solvent based inks used for high volume commercial printing.

OPERATION DESCRIPTION
The assessed polymer will not be manufactured or reformulated in Australia.

Fuel additive products containing the assessed polymer will be manually poured in to the fuel tanks of vehicles.

The assessed polymer will be imported as a component of finished ink products in cartridges, bottles or foil bags. The printer ink will be used for varied printing work in workplace office printers and home office printers. Ink cartridges will be manually fitted into printers and replaced with new ink cartridges as necessary. Printer ink inside ink bottles will be manually transferred into the printer ink tank as required.

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 and storage	2	12-24
Automotive servicing	8	210
Printer operators	0.5-8	210

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the assessed polymer at ≤ 30% concentration in finished fuel additive products or 1-10% in industrial printing inks only in the unlikely event of an accidental breach of the product packaging.

Automotive servicing

Workers may experience dermal and possibly ocular exposure to the assessed polymer at a concentration of up to 30% during transfer of the additive to the fuel tank or in the event of a spill. The use of PPE such as overalls, impervious gloves and safety boots by workers and packaging the products in containers designed to reduce user exposure (small container size of 150 mL and application nozzles designed to fit into fuel tanks) are expected to reduce dermal exposure.

Commercial printing

Workers will install new printer cartridges and remove spent printer cartridges and containers. Significant exposure of workers to the assessed polymer from these operations is not expected as the cartridges and containers are designed to be installed and removed without exposing the operator to the ink inside. When deposited onto paper the ink will dry rapidly and once dry the assessed polymer will be bound to the matrix of the substrates and is not expected to be available for exposure.

Inhalation exposure to the assessed polymer is not expected from either automotive or printing use, given the expected low vapour pressure due to the high molecular weight of the polymer, and the low likelihood of aerosol formation.

6.1.2. Public Exposure

Fuel additive products will be available to the public, and dermal and ocular exposure to the assessed polymer at ≤ 30% may occur to DIY users during transfer of the product to vehicle fuel tanks. The infrequent use of these products by DIY users is expected to limit their exposure to the assessed polymer.

Members of the public may come into contact with materials printed using ink containing the assessed polymer. However, once the ink dries, the assessed polymer will be bound to the matrix of the substrates and is not expected to be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the assessed polymer are summarised in the following table. For details of the studies, refer to Appendix B.

Endpoint	***Result and Assessment Conclusion***
Skin irritation – rabbit	slightly irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, Metabolism and Distribution

Based on the high molecular weight of the assessed polymer (> 1,000 g/mol), and low proportion of low molecular weight species (< 500 g/mol), absorption across biological membranes is expected to be limited.

Inhalation toxicity data are not provided.

Irritation
The assessed polymer was slightly irritating to the skin of rabbits.

Mutagenicity/Genotoxicity
The assessed chemical was non-mutagenic in a bacterial reverse mutation assay.

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

6.3.1. Occupational Health and Safety
Based on limited data available the assessed polymer is of low hazard presenting only as a slight skin irritant.

When adding fuel additives containing the assessed polymer to fuel tanks, workers may be at risk of slight skin irritation effects. Significant inhalation exposure is not expected due to the polymers predicted low vapour pressure, and the low potential for product aerosol formation. The risk from exposure to products containing the polymer at a concentration of up to 30% is expected to be reduced through the control measures in place to minimise worker exposure, including the use of PPE and packaging in containers designed to reduce user exposure.

Exposure to the assessed polymer at a concentration of up to 10% during industrial printing is most likely to occur during ink replacement. However, significant exposure is not expected during these operations as the ink cartridges and containers are designed to prevent operator exposure to the ink during installation and removal.

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
The use of fuel additive containing the assessed polymer at up to 30% concentration also places DIY users at the risk of slight skin irritation from dermal exposure. However, this risk should be reduced through packaging in order to lessen user exposure, specifically packaging in small 150 mL containers with an application nozzle designed to minimise exposure. Inhalation exposure of DIY users is expected to be limited due to the polymers predicted low vapour pressure.

The printing inks containing the assessed polymer will not be made available to the general public. Members of the public may come into contact with materials printed using these inks. However, once the ink is cured, the assessed polymer will be reacted and bound to the matrix of the substrates and is not expected to be available for exposure.

When used in the proposed manner, the assessed polymer is not considered to pose an unreasonable 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 is imported as a component of finished fuel additive products or industrial printing inks. Release may occur from accidental spills during the manual addition to fuel tanks or loading ink into printers. Any accidental spills are to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
The applicant estimates that up to 90% of the import volume of the assessed polymer will be used as a diesel fuel additive, which is expected to be fully combusted during use. A small proportion of the assessed polymer will be used in printing inks where it is expected to cure into the ink matrix and share the fate of the substrate it is applied to.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the assessed polymer is expected to remain in both ink and diesel fuel additive containers which are to be disposed of to landfill along with the containers. Up to 10% of the assessed polymer will be used in printing inks. According to the recent Australian National Waste Report (Blue Environment Ltd., 2018), 60% of the wastepaper treated with the assessed polymer is expected to be recycled domestically, with the remaining 40% expected to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted for the assessed polymer. A majority of the assessed polymer is expected to be fully combusted during its use as a fuel additive. The rest of the assessed polymer used as a component in inks is expected to share the fate of the substrate to which it is applied, to be disposed of to landfill or entered paper recycling plants. During recycling processes, wastepaper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The assessed polymer discharged to wastewater from paper recycling processes is expected to be effectively removed through adsorption to sludge or by flocculation at wastewater treatment plants (Boethling and Nabholz, 1997; Guiney et al., 1997). Minor amounts of the assessed polymer may be disposed of to landfill as collected spills and empty container residues. In landfill, the assessed polymer is expected to have low mobility based on its cationic properties and high molecular weight. The assessed polymer is also not expected to be bioaccumulate due to its high molecular weight. In landfill, the assessed polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water and oxides of carbon, nitrogen and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The use pattern will result in a small portion of the assessed polymer being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 6% release of the assessed polymer into sewer systems nationwide over 365 days per annum. The extent to which the assessed polymer is removed from the effluent in STP processes based on the properties of the assessed polymer has not been considered for this scenario, and therefore no removal of the assessed polymer during sewage treatment processes, is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	6	%
Annual quantity of chemical released to sewer	600.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	1.64	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	0.34	µg/L
PEC – Ocean:	0.03	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The assessed polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.34 µg/L may potentially result in a soil concentration of approximately 2.247×10^{-3} mg/kg. Assuming accumulation of the assessed polymer in soil for 5 and 10 years under repeated irrigation, the concentration of assessed polymer in the applied soil in 5 and 10 years may be approximately 1.124×10^{-2} mg/kg and 2.247×10^{-2} mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were provided for the assessed polymer. The assessed polymer contains cationic functionality with a Functional Group Equivalent Weight (FGEW) < 5000, and is therefore potentially harmful to aquatic organisms in environmental water. However, due to the low water solubility, this effect is not expected to be significant.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration could not be calculated as no ecotoxicity endpoints were provided.

Due to the lack of ecotoxicity data, the assessed polymer cannot be classified under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) for acute and chronic toxicities (United Nations, 2009).

7.3. Environmental Risk Assessment

A risk quotient (Q = PEC/PNEC) was not calculated as a PNEC was unable to be determined.

On the basis of the use pattern and the maximum import volume of 10 tonnes per annum, it is unlikely the assessed polymer will reach ecotoxicologially significant concentrations. Therefore, the assessed polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin Irritation – Rabbit

TEST SUBSTANCE	Assessed polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Male
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks – Method	Patches were removed 4 hours after application.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	1	1	2	< 7 days	0
Oedema	0	0	0	1	< 7 days	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal

Remarks – Results	Very slight to well defined erythema was noted at the 1-hour observation and very slight erythema persisted up to and including at the 72-hourobservation. The treated skin site appeared normal at the 7-day observation. Very slight oedema in 2 animals was noted at the 1 hour observation after patch removal. Brown coloured residual test material was present up to 72 hours after removal of the patch, which did not affect the evaluation of skin reactions. Damage to the skin from removal of the patch was noted at the 1 hour observation in 2 of the animals.
CONCLUSION	The assessed polymer is slightly irritating to the skin.
TEST FACILITY	Safepharm (2005)

B.2. Genotoxicity – Bacteria

TEST SUBSTANCE	Assessed polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria Plate incorporation procedure
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	Test 1 and test 2: with and without metabolic activation: 50, 150, 500, 1,500 and 5,000 µg/plate
Vehicle	tetrahydrofuran
Remarks – Method	The pre incubation procedure was not utilised.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	≥ 5,000	negative
Test 2		> 5,000	≥ 5,000	negative
Present				
Test 1	> 5,000	> 5,000	≥ 5,000	negative
Test 2		> 5,000	≥ 5,000	negative

Remarks – Results

A brown fibrous precipitate was evident at 5,000 µg but it did not prevent assessment of the plates.

No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, either with or without metabolic activation.

A statistically significant increase in revertant colony frequency was observed in strain TA98 (with S9-mix) at 150 µg/plate in test 2. As the counts recorded were in the specified range for this strain, the increase was relatively small, and a dose response relationship was lacking, this result was not considered biologically significant.

The positive controls produced satisfactory responses, confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The assessed polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Safepharm (2005)

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