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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Z-167

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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Director
NICNAS

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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
STD/1632	Lubrizol International Inc.	Z-167	Yes	≤ 80 tonnes per annum	A component of automotive fluids

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Corrosion/Irritation (Category 1B or 1C)	H314 - Causes severe skin burns and eye damage

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute toxicity (Category 3)	H402 - Harmful to aquatic life
Chronic toxicity (Category 3)	H412 - Harmful to aquatic life with long-lasting effects

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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin Corrosion/Irritation (Category 1B or 1C): H314 - Causes severe skin burns and eye damage

  The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

- Due to the corrosive properties of the notified polymer, the notifier should consider their obligations under the Australian Dangerous Goods Code.

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, where possible
  - Use of well ventilated environments

- 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 during reformulation and/or end use processes:
  - 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 during reformulation:
  - Impervious gloves
  - Eye protection
  - Coveralls
  - Respiratory protection if used in poorly ventilated areas or where mists are generated and released

  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.

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.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

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 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 notified polymer will be used as a component of automotive fluids at ≥ 1% concentration.

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 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
Standard: Synthetic polymer with Mn < 1,000 g/mol (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, degree of purity, impurities, additives/adjuvants, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Currently being notified in some other countries

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-167

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is < 500 g/mol

ANALYTICAL DATA
Reference ESI-MS, FTIR, APC, NMR, TGA, UV-Vis, HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear liquid

Property	Value	Data Source/Justification
Melting Point/Pour Point	-21.08 °C	Measured
Boiling Point	240.3 °C at 101.3 kPa	Measured
Density	1,119.3 kg/m^3 at 20 °C	Measured
Vapour Pressure	7.24 × 10^{-5} kPa at 25 °C	Measured
Water Solubility	0.035 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	May be hydrolysed in water	Measured
Partition Coefficient (n-octanol/water)	log Pow is < -1.02 to 4.65	Measured. However the notified polymer is surface active and may therefore be present at the n-octanol/water interface.
Surface Tension	39.8 ± 0.6 mN/m at 20.1 °C	Measured
Adsorption/Desorption	log K_{oc} = < 1.0 to 4.43	Measured
Dissociation Constant	Not determined	Not expected to dissociate in

		environmental pH range of 4-9.
Flash Point	95.1 °C	Measured
Autoignition Temperature	272 °C	Measured
Explosive Properties	Considered negative	Measured
Oxidising Properties	Considered negative	Measured

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

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, 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. The notified polymer will be imported as a component of concentrate/additive package (at ≤ 2% concentration) for reformulation into end use automotive fluids.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-40	40-55	45-55	55-75	70-80

PORT OF ENTRY
Western Australia, Queensland and Victoria

IDENTITY OF MANUFACTURER/RECIPIENTS
Lubrizol International Inc.

TRANSPORTATION AND PACKAGING
The products containing the notified polymer will be imported into Australia and transported via isotainer or containers (~1,250 L). Smaller quantities will be transported in drums (~208 L). Reformulated automotive fluids may be supplied to customers in bulk or in smaller containers.

USE
The notified polymer will be used as a component of automatic transmission fluids (ATFs) and continuous variable transmission (CVT) fluids at < 1% concentration.

OPERATION DESCRIPTION
Reformulation
After importation, it is expected that the additive packages containing the notified polymer at ≤ 2% will be reformulated. They will be transferred into blending tanks (containing mineral oil and other additives) using automated, well ventilated and enclosed processes. After blending, it is expected that the end use products containing the notified polymer will be packaged using automated processes. The resulting ATFs and CVT fluids (transmission fluids) containing the notified polymer at < 1% may be supplied in bulk for industrial users or in smaller containers for use in commercial service applications or by do-it-yourself (DIY) users.

End use
ATFs and CVT fluids containing of the notified polymer will be supplied in bulk to automobile manufacturers who will use it for factory fill applications. The fluids will also be used by commercial automotive and industrial engine service outlets and to a lesser extent by the public (DIY users). Use by the DIY users will involve the transmission fluids being manually decanted into the transmission fluid tank.

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)*
Workers involved in blending operations	1–3	4–5
Workers involved in packaging operations	2–5	1–3
Distribution	0–2	100–225

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified polymer at ≤ 2% concentration only in the event of accidental rupture of containers.

Reformulation

Dermal and ocular exposure to the notified polymer (≤ 2% concentration) is possible when blending operators are 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, and a high degree of automation will minimise exposure to the notified polymer during reformulation.

Transfer of the finished transmission fluids containing the notified polymer at < 1% concentration to packaging will mainly be performed by automated processes; hence, exposure to workers is expected to be minimal. Inhalation exposure is not expected given the enclosed systems and low vapour pressure of the notified polymer. However, respiratory protection is expected to be used in poorly ventilated areas or where mists are generated.

At the reformulation facilities, samples will be taken for quality assurance testing. Dermal exposure to the notified polymer (≤ 2% concentration) may occur during sampling. To minimise exposure, staff are expected to wear gloves, eye protection and long sleeved coats.

End use

Operators at the commercial automotive and industrial engine service outlets may come into contact with the notified polymer at < 1% concentration. The exposure may occur during the manual transfer of ATFs and CVT fluids from the product container into the transmission fluid tank or during the cleaning and maintenance of equipment. It is expected that at these professional end use sites the processes will be mostly enclosed or supplied with engineering controls such as good general ventilation, to reduce exposure from splashes, mists and vapours (if generated). Exposure will be minimised by the use of PPE such as gloves, goggles and protective clothing.

6.1.2. Public Exposure

Dermal and ocular exposure to the notified polymer may occur to members of the public (DIY users) when adding transmission fluids containing the notified polymer at < 1% concentration to vehicles. PPE may not be worn by DIY users. However, given the low concentration (< 1%) of the notified polymer in the products and infrequent nature of DIY use, potential for exposure to the notified polymer is expected to be low.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 2,000 mg/kg bw; low toxicity

Skin irritation (*in vitro*)EPIDERM™ skin corrosion test	corrosive
Rat, repeat dose oral toxicity – 28 days	NOAEL = 700 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic
Genotoxicity – in vitro mammalian cell gene mutation tests	non genotoxic

Toxicokinetics, metabolism and distribution
No data on toxicokinetics for the notified polymer was provided. Based on the low molecular weight (< 500 g/mol), and partition coefficient (log Pow is < -1.02 to 4.65) of the notified polymer, absorption across biological membranes may occur.

Acute toxicity
The notified polymer was found to have low acute oral and dermal toxicity in rats.

Irritation and sensitisation
The notified polymer was corrosive to the skin based on an *in vitro* EPIDERM™ skin corrosion test. Based on the viability levels after 3 minutes and 60 minutes, the test substance is predicted to have a GHS classification of Corrosive 1B or 1C according the OECD test guideline. Irritation effects were also seen in the acute dermal toxicity study and the repeated dose toxicity study.

No ocular irritation or skin sensitisation study was conducted due to the corrosive nature of the notified polymer.

Repeated dose toxicity
In a 28 day repeat dose study by oral gavage with a 14-day recovery period, rats were administered the notified polymer at 35, 175, 350 and 700 mg/kg bw/day. A NOAEL of 700 mg/kg bw/day was established by the study authors, based on the absence of treatment-related, toxicologically-significant effects at all doses tested. The presence of irritating effects in clinical observations and in the non-glandular stomach linked with macroscopic findings were likely based on the corrosive effects of the notified polymer and the oral route of exposure.

Mutagenicity/Genotoxicity
The notified polymer was not considered to be mutagenic in a bacterial reverse mutation assay and was not clastogenic in an *in vitro* mammalian (human lymphocytes) chromosome aberration test or in an *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene.

Health hazard classification
Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin Corrosion/Irritation (Category 1B or 1C)	H314 - Causes severe skin burns and eye damage

The notifier has classified the notified polymer as Skin Corrosion/Irritation (Category 1B) in the SDS provided.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is corrosive but is expected to be of low acute oral and dermal toxicity and not genotoxic. The potential for skin sensitisation is not known. The potential for corrosive or irritating effects to the skin or eyes is expected to be significantly reduced at the proposed low concentrations at which the polymer is imported and used. However some irritation potential is expected at the introduction concentration.

During reformulation, workers may be exposed to the notified polymer as introduced at ≤ 2% 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 < 1% concentration when manually decanting the transmission fluids containing the notified polymer into the transmission fluid tank. 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 transmission fluids containing the notified polymer at < 1% concentration to vehicles. It is not known whether DIY users would use PPE during this process. However due to very low concentration of the notified polymer in end use products corrosive/irritation potential of the notified polymer is expected to be considerably reduced. In addition, the frequency and extent of exposure 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 will be imported as a component of an additive package for reformulation into end use automatic transmission fluids (ATFs) and continuously variable transmission (CVT) fluids. The reformulation process will involve blending the additive package containing the notified polymer with mineral oil and other ingredients in an automated and enclosed process, followed by automated filling of the finished products into end use containers. According to the notifier, similar materials and products are blended in the same equipment; therefore, any residual material left in the blending tank or transfer lines is simply allowed to remain for the next blend. Accidental spills of the notified polymer during reformulation, transport or storage are expected to be collected and disposal of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

ATFs and CVT fluids containing the notified polymer will be used by automobile manufacturers for factory fill applications. They will also be used by commercial automotive and industrial engine service outlets, and to a limited extent by the public (DIY users). Use by the DIY users will involve the transmission fluids being manually decanted into the transmission fluid tank.

At automobile manufacturers and commercial automotive and industrial engine service outlets, used transmission fluids will 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.

ATFs and CVT fluids could be used by the public (DIY users) 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 ~1% (0.04 × 0.3) of all motor oil sold is incorrectly disposed of by DIY users. For ATF and CVT applications, 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. Accordingly < 1% of the notified polymer present in ATF and CVT fluid is expected to be disposed of incorrectly. The notified polymer contained in ATF and CVT fluid 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 notified polymer are expected to be reused or disposal of in accordance with local government regulations.

7.1.2. Environmental Fate

The biodegradability study conducted on the notified polymer shows that it is not readily biodegradable, but shows inherent biodegradability in the aquatic environment (27.4% biodegradation in 28 days). For details of the biodegradability study, refer to Appendix C. The hydrolysis test results show that the notified polymer is possibly hydrolysed in the aquatic environment

Any used or waste fluids containing the notified polymer is expected to be recycled, re-refined or disposed of by authorised waste management facilities. It is likely that the notified polymer will be degraded into simpler compounds during refining. The notified polymer in the environment is expected to eventually degrade into water and oxides of carbon and phosphate 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 notified polymer to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 100 m/L (WAF*)	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	EC50 = 71 mg/L (WAF*)	Harmful to aquatic invertebrates
Algal Toxicity	EC50 = 28 mg/L (WAF*)	Harmful to alga
Inhibition of Bacterial Respiration	EC50 > 1,000 mg/L	Does not inhibit microbial activity in STPs

*WAF: Water Accommodated Fraction

Under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, the notified polymer is expected to be harmful to aquatic invertebrates and alga. Therefore, the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life" under the GHS. Based on the acute toxicity and lack of readily biodegradation, the notified polymer is formally classified as "Chronic Category 3; Harmful to aquatic life with long lasting effects" under the GHS (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a component of automatic transmission fluids (ATFs) and continuous variable transmission (CVT) fluids. On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Pour Point -21.08 °C

Method	Similar to OECD TG 102 Melting Point/Melting Range
Test Facility	EAG, Inc. (2017a)

Boiling Point 240.3 ± 0.75 °C at 101.3 kPa

Method	Similar to OECD TG 103 Boiling Point
Remarks	A Mettler FP-900 Thermosystem and FP81HT MBC Cell were used.
Test Facility	EAG, Inc. (2017a)

Density 1,119.3 kg/m^3 at 20 °C

Method	Similar to OECD TG 109 Density of Liquids and Solids
Remarks	A pycnometer was used.
Test Facility	EAG, Inc. (2017a)

Vapour Pressure 7.24×10^{-5} kPa at 25 °C
6.55×10^{-3} kPa at 83 °C
2.43×10^{-2} kPa at 140 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	A vapour pressure balance was used.
Test Facility	Envigo Research Limited (2017a)

Water Solubility 0.035 g/L at 20 ± 0.5 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method
Test Facility	Envigo Research Limited (2016)

Hydrolysis as a Function of pH

Method	OECD TG 111 Hydrolysis as a Function of pH
Remarks	Results showed an increase of hydrogen ion concentration over time, which indicated possible hydrolysis. The correlation between hydrogen ion concentration and time was stronger at 30°C for each pH level tested, and the strongest correlation was found at pH 7.
Test Facility	EAG, Inc. (2017b)

Partition Coefficient (n-octanol/water) log P_{ow} is < -1.02 to 4.65

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient. US EPA OPPTS 830.7570 Partition Coefficient.
Remarks	The test substance is surface active. Under the chromatographic conditions of the HPLC Method, the test substance was eluted as 3 peaks on the evaporative light scattering detector. The corresponding mean offset adjusted log P_{OW} for the test substance ranged from unretained (< -1.02) to 4.65.
Test Facility	EAG, Inc. (2017c)

Surface Tension 39.8 ± 0.6 mN/m at 20.1 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions
Remarks	Test solution concentration was at 90% of the saturation solubility. The test substance was surface active.

Test Facility EAG, Inc. (2017a)

Adsorption/Desorption log K_{oc} = < 1.0 to 4.43

Method OECD TG 121 Adsorption Coefficient
EC Council Directive 2001/59/EC C.19 Adsorption Coefficient
Remarks The test substance is surface active. Under the chromatographic conditions of the HPLC method, the test substance was eluted as 3 peaks on the evaporative light scattering detector. The corresponding mean offset adjusted log K_{oc} for the test substance ranged from unretained (< 1.0) to 4.43.
Test Facility EAG, Inc. (2017d)

Flash Point 95.1 ± 1.0 °C

Method Similar to EC Council Regulation No 440/2008 A.9 Flash Point
Remarks A Koehler Model K-16200 Pensky-Martens Closed-Cup Flash Tester was used with a heating block equipped with propane tank and rubber tubing to deliver the propane fuel that produced the flame for the flash point test.
Test Facility EAG, Inc. (2017a)

Autoignition Temperature 272 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases)
Remarks No cool flames were noted. Ignition produced an orange flame.
Test Facility Dekra Insight (2017)

Explosive Properties Considered negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks No reaction at 40 J was noted for the test substance when BAM Fallhammer System 1 was used. The test substance did not exhibit an explosion during any of the tests when Koenen Tube System 1 was used.
Test Facility Dekra Insight (2017)

Oxidizing Properties Considered negative

Method EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids)
Remarks The test substance had a mean pressure rise time greater than that observed for the nitric acid reference sample. Therefore it was not considered to be an oxidising liquid.
Test Facility Dekra Insight (2017)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method (2001)
Species/Strain	Rat/Crl:CD(SD)
Vehicle	None
Remarks - Method	No protocol deviations. No sighting study was conducted.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	1 F	300	0/1
2	1 F	2,000	0/1
3	4 F	2,000	0/4

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No adverse clinical signs were noted in the animal tested at 300 mg/kg bw. Test substance-related clinical findings of impaired use of hindlimbs, cool body, and ataxia were noted for one animal dosed at 2000 mg/kg bw at approximately 1 hour after dose administration. Other clinical observations in the 2,000 mg/kg bw group consisted of clear ocular discharge, yellow material on the anogenital and/or urogenital areas, salivation, and/or red material around the nose at approximately 1, 2, and/or 4 hours after dose administration on day 0; the yellow and/or red material findings were also noted during days 1-4. All effects in the 2,000 mg/kg bw group disappeared by day 5.
Effects in Organs	There were no macroscopic findings at the scheduled necropsy.
Remarks - Results	Body weight changes were as expected during the study.

CONCLUSION	The notified polymer is of low acute toxicity via the oral route.
TEST FACILITY	Charles River Laboratories (2017a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity (1987)
Species/Strain	Rat/Crl:CD(SD)
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	No clinical observations were noted during the study.
Signs of Toxicity - Systemic	All males had very slight or slight erythema during days 1-2. During days 3-6, very slight erythema and/or oedema with desquamation was noted in all males. During days 10-11, 1 male had scabbing at the dose site and 2 males had desquamation. No signs of irritation were observed for males during days 7-9 and days 12-14.

	Very slight or slight erythema was observed for 4 of 5 females on day 1 and for all females on day 2. All females had very slight or slight erythema and/or oedema with desquamation during days 3-6; additionally, 2 females had scabbing at the dose site on day 3. During days 10-11, 3 females were noted with desquamation and/or scabbing at the dose site. On day 14, 1 female was noted with scabbing at the dose site.
Effects in Organs	There were no macroscopic findings at the scheduled necropsy.
Remarks - Results	There were no remarkable body weight changes in rats. Skin irritation effects were seen, which were resolved in all but one animal by day 14.
CONCLUSION	The notified polymer is of low acute toxicity via the dermal route.
TEST FACILITY	Charles River Laboratories (2017b)

B.3. Irritation – skin (*in vitro* EPIDERM™ Skin Corrosion Test)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 431 *In vitro* Skin Corrosion - Human Skin Model Test (2015)
Vehicle	None
Remarks - Method	No protocol deviations. The negative control was sterile distilled water, and the positive control was 8N potassium hydroxide.

RESULTS

3 min exposure

Test material	*Mean OD_{570} of duplicate tissues*	*SD of Mean OD_{570}*	*Relative mean Viability (%)*
Negative control	1.873	0.039	100
Test substance	1.587	0.164	84.7
Positive control	0.068	0.004	3.6

60 min exposure

Test material	*Mean OD_{570} of duplicate tissues*	*SD of Mean OD_{570}*	*Relative mean Viability (%)*
Negative control	1.701	0.177	100
Test substance	0.104	0.033	6.1
Positive control	0.068	0.018	4.0

Remarks - Results	The MTT solution containing the test substance did not turn blue/purple, showing that the test substance did not reduce MTT. The solution containing the test substance did not become coloured, showing that the test substance did not have the potential to cause colour interference. The acceptance criteria for the negative control, positive control and coefficient of variation between the two tissue replicates of each treatment group were satisfied. Based on the viability levels after 3 minutes and 60 minutes, the test substance is predicted to be corrosive, warranting a GHS classification of Corrosive 1B or 1C.
CONCLUSION	The notified polymer was corrosive to the skin under the conditions of the test.

TEST FACILITY Envigo Research Limited (2017b)

B.4. Repeat dose toxicity

TEST SUBSTANCE Notified polymer

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents

Species/Strain	
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Polyethylene glycol 400 (PEG400)
Remarks - Method	Minor protocol deviations in animal husbandry, portmortem and pathology were considered not to have compromised the validity or integrity of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
control	5 per sex	0	1 F
low dose	5 per sex	35	1 F
mid dose	5 per sex	175	0/10
mid high dose	5 per sex	350	0/10
high dose	5 per sex	700	0/10
control recovery	5 per sex	0	0/10
high dose recovery	5 per sex	700	0/10

Mortality and Time to Death

No unscheduled deaths were attributed to the administration of test substance. One female in the control group was killed humanely on day 16 with macroscopic and microscopic findings consistent with gavage error. It was considered an accidental death. One female in the 35 mg/kg bw/day group was dead on day 14 and had no macroscopic and microscopic findings. The cause of death was not determined.

Clinical Observations

Test substance related yellow material around the mouth was observed in the animals in the 700 mg/kg bw/day group at irregular intervals during the dosing period. Clear material around the mouth and yellow material in the urogenital area was observed in the females at the same dose level. These findings disappeared during the recovery.

Body weights, food consumption, functional observational battery, including home cage observations, handling observations, open field observations, sensory observations, neuromuscular observations, physiological observations, and motor activity were not affected by the test substance administration.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Test substance related, statistically significant lower mean urine pH was observed in the 350 and 700 mg/kg bw/day group females after the 28-day exposure. These effects disappeared in the 700 mg/kg bw/day group females after the recovery period. Other statistically significant differences in urine parameters (specific gravity in males at 700 mg/kg bw/day after recovery) were not considered to be test substance related by the study authors.

Haematology, coagulation and serum chemistry parameters were not affected by the test substance administration. Statistically significant differences in serum chemistry (mean albumin, glucose potassium for males at 700 mg/kg bw/day after recovery, SDH for males at 35, 175, 350 and 700 mg/kg bw/day after exposure, albumin for females at 350 and 700 mg/kg bw/day after exposure) parameters were not considered test substance related. These effects were attributed by study authors to biologic variation within historical control values because of lacking correlations with other related clinical pathology changes or dose-response.

Effects in Organs

Some statistically significant differences in organ weights were observed at the scheduled necropsies, including

lower mean absolute brain weights in the 35 and 700 mg/kg bw/day group males. The differences were attributed to biological variability within historical control values rather than test substance related as there were no microscopic correlates or a dose response relationship.

Test substance related findings (thickened stomach and yellow contents) in the non-glandular stomach were noted at 175 mg/kg bw/day (3 males and all females), 350 mg/kg bw/day (all males and females) and 700 mg/kg bw/day (all males and females) after the exposure period, and were linked to microscopic changes. These findings were considered to be due to tissue irritation.

Increased incidence of hyaline droplet accumulation was observed in kidneys of male animals at 175 mg/kg bw/day (2 animals), 350 mg/kg bw/day (3 animals) and at 700 mg/kg bw/day (4 animals). While the composition of the hyaline droplets was not identified, in male rats the presence of hyaline droplets is often associated with accumulation of alpha-2μ globulin and is a male rat-specific finding not occurring in female rats or other species, including primates. There were no other test substance related histopathologic changes at the scheduled necropsies.

At necropsy after recovery, higher mean adrenal gland weight (relative to brain weight) and lower thymus weight (absolute and relative to final body and brain weights) were observed in the 700 mg/kg bw/day group males and higher absolute mean ovaries/oviducts weights were observed in the 700 mg/kg/day group females. The differences were not observed after the 28-day exposure and weights were within the historical control database range.

No other histopathological changes were observed at the scheduled necropsies.

Remarks – Results
Test substance-related systemic effects were not identified in the study.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 700 mg/kg bw/day by the study authors as all findings were considered non-adverse.

TEST FACILITY Charles River Laboratories (2017c)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997)
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	10% rat liver S9 homogenate metabolising system (induced with phenobarbital / β-naphthaflavone)
Concentration Range in Main Test	With or without metabolic activation: 0, 1.5, 5, 15, 50, 150, 500, 1,500 and 5,000 μg/plate
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	No protocol deviations. No preliminary test was conducted.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 1,500	> 5,000	negative
Test 2	≥ 5,000	> 5,000	negative
Present			
Test 1	≥ 1,500	> 5,000	negative
Test 2	≥ 5,000	> 5,000	negative

Remarks - Results	No positive mutagenicity responses or concentration-related increases in revertants were noted with any of tester strains in either the presence or absence of S9 activation. No test substance precipitate was observed on the plates at any of concentrations tested in either the presence or absence of S9-mix. In test 1, there was a visible reduction in the growth of the bacterial background lawns of TA 100 in the absence of S9-mix, from 1,500 to 5,000 µg/plate to TA 1535 (in the absence of S9-mix) and TA 100 and TA1535 in the presence of S9-mix. In test 2, a similar toxic response was noted with reduced bacterial background lawns noted to TA100 and TA1535 at 5,000 µg/plate in both the presence and absence of S9-mix. No toxicity was observed to any of the remaining bacterial tester strains in either the absence or presence of S9-mix. The concurrent positive and negative controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Envigo Research Limited (2017c)

B.6. Genotoxicity – *in vitro* Mammalian Cell Gene Mutation Tests using The Thymidine Kinase Gene

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 490 *In vitro* Mammalian Cell Gene Mutation Tests using The Thymidine Kinase Gene (2016) EC Directive 2000/32/EC B.17 Mutagenicity - *In vitro* Mammalian Cell Gene Mutation Test
Cell Type/Cell Line	L5178Y TK +/- 3.7.2c mouse lymphoma cells (heterozygous at the thymidine kinase locus)
Metabolic Activation System	2% rat liver S9 homogenate metabolising system (induced with phenobarbital / β-naphthaflavone)
Vehicle	DMSO
Remarks - Method	No protocol deviations. The maximum dose level used in the main test was limited by test substance induced toxicity.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0, 10. 20, 40, 60, 80, 100	4 h	2 d	10-12 d
Test 2	0, 40, 80, 100, 120, 160, 200	24 h	2 d	10-12 d
Present				
Test 1	0, 40, 80, 100, 120, 140, 160	4 h	2 d	10-12 d

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 156.25			
Test 1		> 80	> 100	negative
Test 2		> 160	> 200	negative
Present	> 156.25			
Test 1		> 120	> 160	negative

Remarks - Results	In the 4-hour exposure in the absence of metabolic activation, the 120 and 160 µg/mL concentration levels were not plated out for 5-TFT resistance and viability due to excessive toxicity. In the 4-hour exposure in the presence of metabolic activation, at 160 µg/mL, and in the 24-hour exposure in the absence of metabolic activation, at 200 µg/mL although these concentration levels were plated out for 5-TFT resistance and viability, they were not included in the analysis due to excessive toxicity. The test substance did not induce any toxicologically significant increases in the mutant frequency at any of the concentration levels in three exposure groups. The Global Evaluation Factor (GEF) value of the test substance concentration levels was not exceeded in any of the three concentration groups. No precipitate of the test substance was observed throughout the main test. The concurrent positive and negative controls produced satisfactory responses, thus confirming the validity of the test.
CONCLUSION	The notified polymer was not clastogenic to the TK +/- locus in L5178Y cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Envigo Research Limited (2017d)

B.7. Genotoxicity – *in vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test (2016)
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	2% rat liver S9 homogenate metabolising system (induced with phenobarbital / β-naphthaflavone)
Vehicle	DMSO
Remarks - Method	No protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 10, 20, 40*, 80*, 100*, 120, 160	4 h	20 h
Test 2	0*, 20, 40, 80*, 160*, 200*, 240*, 320	24 h	24 h
Present			
Test 1	0*, 20, 40*, 80*, 160*, 200, 240, 320	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 78.13			
Test 1		> 100	> 160	negative
Test 2		≥ 240	> 320	negative
Present	> 156.25			
Test 1		> 160	> 320	negative

Remarks - Results	The test substance did not induce any statistically significant increases in the frequency of cells with aberrations or in the numbers of polyploid cells at any concentration level in any of the three exposure groups, either in the absence or presence of metabolic activation. No precipitate was observed at the levels used in the main test, however

	was evident in the preliminary test from 1250 µg/mL. Haemolysis was observed at the end of exposure at 160 µg/mL in the 4-hour exposure in the absence of S9, at and above 80 µg/mL in the 4-hour exposure in the presence of S9 and at 320 µg/mL in the 24-hour exposure group. Optimum toxicity in the 4-hour exposure groups was achieved at 100 µg/mL in the absence of S9 with 49% mitotic inhibition, and at 160 µg/mL in the presence of S9 with 50% inhibition of the mitotic index. The 24-hour exposure group showed 39% and 75% mitotic inhibition at 200 µg/mL and 240 µg/mL respectively. The concurrent positive and negative controls produced satisfactory responses, thus confirming the validity of the test.
CONCLUSION	The notified polymer was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	Envigo Research Limited (2017e)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test EC Directive 92/69/EEC C.4-C CO_2 Evolution Test
Inoculum	Activated sludge from a local STP
Exposure Period	29 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 by titration
Remarks - Method	No significant deviations from the test guidelines were reported. The test substance was directly added to the test vessels. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	0.37	5	27.8
8	9.13	8	77.6
12	16.1	12	86.1
23	24.1	23	93.9
29	27.4	29	96.1

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 27.4%.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	EAG, Inc. (2017e)

C.2. Ecotoxicological Investigations

Preliminary Comment
The endpoints in all of the ecotoxicicological studies in this appendix are in terms of nominal Water Accommodated Fraction (WAF) concentrations as this is the most representative of the scenarios of how aquatic organisms could be exposed to the test substance.

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static US EPA OPPTS 850.1075 Fish, Acute Toxicity Test – Static
Species	*Pimephales promelas*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	144 mg $CaCO_3$/L
Analytical Monitoring	Inductively coupled plasma atomic emission spectrometry (ICP-AES)
Remarks – Method	No significant deviations from the test guidelines were reported. Due to potential low aqueous solubility and complex nature of the test substance, the test was done using Water Accommodated Fraction (WAF).

Appropriate amounts of the test substance were weighed and rinsed with a portion of dilution water into bottles and stirred for 3 hours. The solutions were allowed to stand for 2 hours before decanting the aqueous phase or WAF. The aqueous fractions were then filtered into each test chamber through glass wool. The concentration of the test substance was verified by chemical analysis at 0, 48 and 96 hours. During the test, dissolved oxygen was ≥ 8.6 mg/L at 14°C (≥ 83% saturation).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*
Nominal	*Initial measured*		*96 h*
Control	< LOQ*	14	0
6.3	6.3	14	0
13	13	14	0
25	26	14	0
50	48	14	0
100	87	14	0

**The method limit of quantitation (LOQ) was defined as 0.097 mg/L*

LL50	> 100 mg WAF/L at 96 hours based on nominal WAF concentration. At the end of the settling period, all test solutions appeared clear and colourless; however, slight oil sheen on the water surface was visible for the 13 mg/L solution, and increasing amount of oil droplets on surface and at the bottom of the WAF bottle was observed for the 25, 50 and 100 mg/L solutions.
Remarks – Results	All validity criteria for the test were satisfied. Although no mortality was observed among fish in any of the treatment groups, several fish in 100 mg WAF/L treatment group were observed to be lethargic.

CONCLUSION The test substance is not harmful to fish up to its water solubility limit.

TEST FACILITY EAG, Inc. (2016)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static US EPA OPPTS 850.1010 Aquatic Invertebrate Acute Toxicity Test, Freshwater *Daphnids*
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	152 mg $CaCO_3$/L
Analytical Monitoring	Inductively coupled plasma atomic emission spectrometry (ICP-AES)
Remarks - Method	No significant deviations from the test guidelines were reported. Due to the potential low aqueous solubility and complex nature of the test substance, the test was done using Water Accommodated Fraction (WAF). Appropriate amounts of the test substance were weighed and rinsed with a portion of the dilution water into bottles and stirred for 3 hours. The solutions were allowed to stand for 2 hours before decanting the aqueous phase or WAF. The aqueous fractions were then filtered into each test chamber through glass wool. The concentration of the test substance was verified by chemical analysis at 0 and 48 hours. During the test, dissolved oxygen was ≥ 8.3mg/L at 20°C (≥ 91% saturation).

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Initial measured*		*24 h*	*48 h*
Control	< LOQ*	20	0	0
13	8.9	20	0	0
25	18	20	3	4
50	19	20	2	2
100	47	20	8	9
200	158	20	5	7

**The method limit of quantitation (LOQ) was defined as 0.097 mg/L*

LL50	71 mg WAF/L at 48 hours (extrapolated by probit analysis, the moving average method, and binomial probability with nonlinear interpolation)
Remarks - Results	All validity criteria for the test were satisfied. At the end of settling period, the 13, 25, and 50 mg/L solutions appeared clear and colourless with oil globules on the bottom of the WAF bottle and on the water surface, increasing proportionally with concentration. The 100 mg/L solution appeared slightly translucent with oil globules on the bottom of the WAF bottle and on the water surface. The 200 mg/L solution appeared cloudy and slightly white with oil globules on the bottom of the WAF bottle and on the water surface.
CONCLUSION	The test substance is harmful to aquatic invertebrates.
TEST FACILITY	EAG, Inc. (2017f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Directive 92/69/EEC C.3 Alga Inhibition Test
Species	*Raphidocelis subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: Control, 1.9, 6.1, 20, 63, 200 mg/L Initial measured: < LOQ, 1.82, 4.15, 9.14, 52.6, 178 mg/L
Auxiliary Solvent	None
Water Hardness	Not provided
Analytical Monitoring	Inductively coupled plasma atomic emission spectrometry (ICP-AES)
Remarks - Method	No significant deviations from the test guidelines were reported. Due to the potential low aqueous solubility and complex nature of the test substance, the test was done using Water Accommodated Fraction (WAF). Appropriate amounts of the test substance were weighed and rinsed with a portion of the dilution water into bottles and stirred for 3 hours. The solutions were allowed to stand for 2 hours before decanting the aqueous phase or WAF. The aqueous fractions were then filtered into each test vessel through glass wool. The concentration of the test substance was verified by chemical analysis at 0 and 72 hours.

RESULTS

Biomass		*Growth*	
EL50 mg WAF/L at 72 h	*NOELR mg WAF/L at 72 h*	*EL50 mg WAF/L at 72 h*	*NOELR mg WAF/L at 72 h*
28	6.1	40	6.1

Remarks - Results	All validity criteria for the test were satisfied. The mean cell density in the control increased by 353 times. At the end of settling period, all test solutions appeared clear and colourless; however, clear oily globules were visible on the surface of the 20, 63, and 200 mg/L test solutions.

CONCLUSION	The test substance is harmful to alga.
TEST FACILITY	EAG, Inc. (2017g)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Activated sludge from a local STP
Exposure Period	3 hours
Concentration Range	Nominal: 10, 100, 1,000 mg/L
Remarks – Method	No significant deviations from the test guidelines were reported. Appropriate amounts of the test substance were added into the test medium to achieve the nominal test concentrations.
RESULTS	
IC50	> 1,000 mg/L
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The test substance does not inhibit microbial activity in STPs.
TEST FACILITY	EAG, Inc. (2017h)

BIBLIOGRAPHY

Aither (2013) Third Independent Review of the Product Stewardship (Oil) Act 2000. Canberra, Australia.

Charles River Laboratories (2017a) [Notified Polymer]: An Acute Oral Toxicity Study in Albino Rats (Fixed Dose Procedure) (Laboratory Project ID WIL-168274, April 2017). Charles River Laboratories, Ashland OH 44805, Unites States (Unpublished report submitted by the notifier).

Charles River Laboratories (2017b) [Notified Polymer]: An Acute Dermal Toxicity Study in Albino Rats (Laboratory Project ID WIL-168275, April 2017). Charles River Laboratories, Ashland OH 44805, Unites States (Unpublished report submitted by the notifier).

Charles River Laboratories (2017c) [Notified Polymer]: A 28-Day Toxicity Study by Oral Gavage in Sprague Dawley Rats with a 14-Day Recovery Period and with Functional Observational Battery and Motor Activity Determinations (Laboratory Project ID WIL-168279, September 2017). Charles River Laboratories, Ashland OH 44805, Unites States (Unpublished report submitted by the notifier).

EAG, Inc. (2016) [Notified Polymer]: A 96-Hour Static Acute Toxicity Test with the Fathead Minnow *Pimephales promelas* (EAG Project No. 331A-138, December 2016). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

Dekra Insight (2017) [Notified Polymer]: Physicochemical Testing (CTL Study Plan No. GLP3016000913, March 2017). Dekra Insight, Process Safety Laboratories, Chilworth Technology Ltd, Southampton Science Park, Southampton, UK (Unpublished report submitted by the notifier).

EAG, Inc. (2017a) [Notified Polymer]: Determination of Melting Point (Pour Point), Boiling Point, Density, Surface Tension, Flash Point and pH (EAG Study No. 84984, February 2017). Analytical Bio-Chemistry Laboratories, Inc., a wholly owned subsidiary of EAG, Inc. Columbia, Missouri 65201, USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017b) [Notified Polymer]: Evaluation of Hydrolysis as a Function of pH (EAG Study No. 84989, August 2017). Analytical Bio-Chemistry Laboratories, Inc., a wholly owned subsidiary of EAG, Inc. Columbia, Missouri 65201, USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017c) [Notified Polymer]: Estimation of n-Octanol/Water Partition Coefficient Using High Performance Liquid Chromatography (EAG Project No. 331C-109, March 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017d) [Notified Polymer]: Estimation of Adsorption Coefficient Using High Performance Liquid Chromatography (EAG Project No. 331C-110, March 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017e) [Notified Polymer]: Ready Biodegradability by the Carbon Dioxide Evolution Test Method (EAG Project No. 331E-143, June 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017f) [Notified Polymer]: A 48 Hour Static Acute Toxicity Test with the Cladoceran *Daphnia magna* (EAG Project No. 331A-143, July 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017g) [Notified Polymer]: A 72 Hour Toxicity Test with the Freshwater Alga *Raphidocelis subcapitata* (EAG Project No. 331P-101, August 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

EAG, Inc. (2017h) [Notified Polymer]: An Activated Sludge Respiration Inhibition Test (EAG Project No. 331E-144, June 2017). EAG Laboratories, Easton, Maryland 21601 USA (Unpublished report submitted by the notifier).

Envigo Research Limited (2016) [Notified Polymer]: Determination of Water Solubility (Envigo Study No. VJ96WR, August 2016). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

Envigo Research Limited (2017a) [Notified Polymer]: Determination of Vapour Pressure (Envigo Study No. WY31GV, October 2017). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

Envigo Research Limited (2017b) [Notified Polymer]: *In vitro* EPIDERM™ Skin Corrosion (Envigo Study No. JY63FG, June 2017). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

Envigo Research Limited (2017c) [Notified Polymer]: Reverse Mutation Assay 'Ames Test' Using Salmonella Typhimurium and Escherichia Coli (Envigo Study No. JT47BD, March 2017). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

Envigo Research Limited (2017d) [Notified Polymer]: L5178Y TK +/- Mouse Lymphoma Assay (Envigo Study No. XJ24KH, March 2017). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

Envigo Research Limited (2017e) [Notified Polymer]: Chromosome Aberration Test in Human Lymphocytes *in vitro* (Envigo Study No. KB55NS, April 2017). Envigo Research Limited, Shardlow Business Park, Shardlow, Derbyshire, DE72 2GD, UK (Unpublished report submitted by the notifier).

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >