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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Z-143

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1761	Lubrizol International Inc	Z-143	Yes	< 100 tonnes per annum	Component of lubricants

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As limited data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the 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.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute (Category 3)	H402 - Harmful to aquatic life
Chronic (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 PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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
- 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:
 - 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:
 - Protective clothing, impervious gloves and eye protection

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

- A copy of the (M)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 for the 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

- The notified polymer in oil products should be disposed of in accordance with local regulations for recycling, re-use or recovery.

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 polymer 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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of lubricants, 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.

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Lubrizol International Inc (ABN: 52 073 495 603)
28 River Street
SILVERWATER NSW 2128

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: freezing point, flammability and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US EPA (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-143

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference NMR, IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

75%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: dark brown viscous liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	Introduced in liquid formulation
Boiling Point	Not determined	Measured, decomposes at 300 °C at 98.1 kPa
Density	934 kg/m ³ at 20 °C	Measured
Vapour Pressure	6.9 × 10 ⁻⁵ kPa at 75 °C (extrapolates to 3.7 × 10 ⁻⁷ kPa at 25 °C)	Measured
Water Solubility	< 9.5 × 10 ⁻⁴ g TOC/L at 20 °C	Measured
Water Extractability	< 0.934 mg/g at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified polymer is not expected to be significantly hydrolysed in

Partition Coefficient (n-octanol/water)	log Pow > 10	the environmental pH range (4 – 9). Measured
Adsorption/Desorption Dissociation Constant	log K _{oc} > 5.63 Not determined	Measured The notified polymer has potential to be ionised under normal environmental conditions (pH 4 – 9)
Flash Point	192.3 ± 2 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be flammable based on the flash point
Autoignition Temperature	372 ± 5 °C	Measured
Explosive Properties	Predicted negative	Based on the structure of the notified polymer
Oxidising Properties	Predicted negative	Based on the structure of the notified polymer

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is 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 for the 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 be introduced into Australia as manufactured (75% in mineral oil) or as a component of lubricant additives at 20-30% concentration.

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

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

PORT OF ENTRY

Western Australia, Queensland and Victoria

IDENTITY OF MANUFACTURER/RECIPIENTS

Recipient: Lubrizol International Inc.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by sea, as manufactured (75% in mineral oil) or as a component of lubricant additives at 20-30% concentration, in 205 L steel drums or 20 MT isotainers. The products containing the notified polymer will be transported by road or rail from the wharf to customer sites for reformulation.

USE

The notified polymer will be used as a component (5-10%) of engine lubricants for marine diesel applications.

OPERATION DESCRIPTION

After importation products containing the notified polymer will be blended with other components into additive packages. The additive packages will be pumped into drums, isotainers or smaller aftermarket containers for transport. End-use products are expected to contain 5-10% notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified polymer ($\leq 75\%$) only in the event of accidental rupture of containers.

The blending process will be automated or semi-automated in a closed system; however, plant operators may be exposed (dermal and ocular) to the notified polymer at up to 75% concentration during opening of containers and connection of pipes when pumping into blending or storage tanks. Other workers may also come into contact with the notified polymer during maintenance, cleaning, sampling and repacking.

Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including protective aprons, nitrile or neoprene gloves and boots and long sleeve clothing, as anticipated by the notifier in the application dossier. Inhalation exposure is not expected given the measured low vapour pressure of the notified polymer.

6.1.2. Public Exposure

The public is not expected to come into contact with products containing $\geq 20\%$ notified polymer which will be used for reformulation in industrial settings. The public may come into contact with end-use lubricants containing $\leq 10\%$ notified polymer in the case of a do-it-yourself (DIY) oil change on a marine vessel's engine. In these cases, dermal and ocular exposure may occur; however, such exposure is expected to be of a short-duration and infrequent basis.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer or an acceptable analogue (Analogue 1, identity in Exempt Information) are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation*	slightly irritating
Rabbit, eye irritation*	slightly irritating

* Test substance was Analogue 1.

Toxicokinetics, metabolism and distribution.

No data on toxicokinetics for the notified polymer was provided. The notified polymer has a high molecular weight (> 1000 Da) and high partition coefficient ($\log P_{ow} > 10$); hence absorption across biological membranes is not expected.

Acute toxicity.

The notified polymer was found to be of low acute toxicity via oral route in rats ($LD50 > 2000$ mg/kg bw).

Irritation and sensitisation.

No skin or eye irritation data for the notified polymer were submitted. Analogue 1 was found to be slightly irritating to skin and eyes of rabbits. The notifier states in the submitted MSDS that prolonged or repeated skin contact with the notified polymer may cause dermatitis.

No sensitisation data for the notified polymer was provided. The notified polymer contains imide and diamine functional groups which are associated with sensitisation. Therefore, the potential of the notified polymer for irritation and sensitisation cannot be ruled out, although it would be limited by the expected low absorption.

Health hazard classification

As limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The greatest risk posed by the notified polymer is the potential for irritation and sensitisation. Exposure to workers during reformulation should be limited by enclosed and automated/semi-automated processes. The risk to the health of workers is expected to be further mitigated by the notifier stated use of personal protective equipment including protective aprons, impermeous gloves, goggles and boots.

Workers most at risk of potential irritating and sensitising effects will be professionals when handling products containing the notified polymer at 5-10% concentration that do not use PPE during marine engine servicing. However, the risk is expected to be limited given the infrequent accidental ocular/skin exposure and the lower concentration of the notified polymer in the products.

Given the lower end-use concentration and stated controls in place to minimise exposure during reformulation, the risk to the health of workers is not considered unreasonable.

6.3.2. Public Health

The public (DIY users) may be at risk of slight eye irritating and/or potential sensitising effects while servicing their own marine diesel engines with products containing the notified polymer at 5-10% concentration through accidental ocular and/or skin exposure. However, given the infrequent use of the products containing the notified polymer by the public and the low concentration of the notified polymer in the products, the risk to the general public 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 not be manufactured in Australia. No environmental release is expected during the highly automated blending process. The blending equipment is expected to be cleaned with oil and the washings containing the notified polymer are expected to be reused in another batch of blending. Any spills of the notified polymer are expected to be re-used.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a component of engine lubricants for marine vessels. For engine oil applications, the majority of oil changes take place in specialised service centres. Release of the notified polymer from professional activities is expected to be limited by the requirement for appropriate disposal of waste oil according to State/Territory regulations. It is estimated using a common assumption, that of the engine oil containing the notified polymer to be changed by 'do-it-yourself' (DIY) enthusiasts, that 5% may be released to sewers and storm water drains from improper disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

Isotainers and empty drums are expected to be sent for cleaning and reconditioning by a licensed company. The washings containing the notified polymers are expected to be treated within an onsite wastewater treatment facility. Used oil, drained from engines, is expected to be recycled, re-refined or used as low grade burner fuel or disposed of according to State/Territory regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is not expected to be readily biodegradable based on its chemical structure. Most of the notified polymer in engine lubricant will be either thermally decomposed during use, recycled or refined. Waste waters containing the notified polymer from onsite wastewater treatment or from improper disposal, may be released to the sewer and directed to a local sewage treatment plant (STPs). In STPs, up to 90% of the notified polymer is expected to partition to sludge due to its high molecular weight and potential cationicity (Boethling and Nabholz, 1997). Sludge from the wastewater treatment plants containing the notified polymer is expected to be disposed of to landfill or applied to agricultural soils. Any notified polymer released to surface water is expected to partition to organic material or sludge/sediment based on its high molecular weight, low water solubility and potential cationicity. The notified polymer is expected to be neither bioaccumulative nor bioavailable to aquatic organisms, due to its high

molecular weight and very low water solubility. A small amount of the notified polymer is expected to be sent to landfill as residues in containers or as a component of waste oil. In landfill, the notified polymer is not expected to be mobile due to its high molecular weight, low water solubility and potential cationicity. The notified polymer is expected to ultimately be degraded into water and oxides of carbon and nitrogen by thermal decomposition or by natural processes in water, soil and landfill.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use as marine vessel engine lubricant, it is estimated for the worst case that 5% of the total import volume of the notified polymer may be released to the sewer from DIY use. It is anticipated that such releases may occur on a nationwide basis over 365 days per year. Conservatively, it is assumed that 0% of the notified polymer will be removed to sludge during sewerage treatment plant (STP) processes.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.7	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.03	µg/L
PEC - Ocean:	0.30	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 3 µg/L may potentially result in a soil concentration of approximately 20.2 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 101 µg/kg and 201.9 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigation conducted on the notified polymer is summarised in the table below. Details of the study can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Algal Toxicity (72 h)	E _r C ₅₀ = 29 mg/L	Harmful to algae

The notified polymer is considered to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified polymer is formally classified as Acute Category 3; Harmful to aquatic life. Based on the acute toxicity and the lack of ready biodegradability data for the notified polymer, it has been formally classified under the GHS as Chronic Category 3; Harmful to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the only test species (algae, E_rC₅₀) for the notified polymer. An acute ecotoxicity endpoint from only one trophic level is available. Therefore, an assessment factor of 1000 has been used.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>	
EC ₅₀	29 mg/L
Assessment Factor	1000

PNEC: 29 µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following risk quotient (Q) has been calculated:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	3.03	29	0.104
Q - Ocean:	0.30	29	0.010

The risk quotients ($Q = \text{PEC}/\text{PNEC}$) have been calculated to be less than 1 for both the riverine and marine compartments. Release of the notified polymer in treated effluent to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. If released to surface waters, the notified polymer is not expected to either be significantly bioavailable or bioaccumulative. Therefore, based on the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Boiling Point** Not determined

Method EC Council Regulation No 440/2008 A.2 Boiling Temperature.
 Remarks The notified polymer started to decompose at approximately 300 °C at 98.1 kPa
 Determined by differential scanning calorimetry
 Test Facility Harlan (2014a)

Density 934 kg/m³ at 20 ± 0.5 °C

Method OECD TG 109 Density of Liquids and Solids.
 EC Council Regulation No 440/2008 A.3 Relative Density.
 Remarks Determined by pycnometer
 Test Facility Harlan (2014a)

Vapour Pressure 6.9 × 10⁻⁵ kPa at 75 °C (extrapolates to 3.7 × 10⁻⁷ kPa at 25 °C)

Method OECD TG 104 Vapour Pressure.
 EC Council Regulation No 440/2008 A.4 Vapour Pressure.
 Remarks Determined by vapour pressure balance
 Test Facility Harlan (2014b)

Water Solubility < 9.5 × 10⁻⁴ g TOC/L at 20 °C

Method OECD TG 105 Water Solubility.
 Remarks Flask Method. The study author considered that the analysed organic carbon content of the samples was not predominantly the main test items components, as these components were expected to be essentially insoluble in water based on chemical structure. Other detection techniques were too inconsistent to be used to determine the definitive water solubility. Thus, the water solubility of the test item measured as total organic carbon (TOC) was determined to be < 9.5 × 10⁻⁴ g at 20 °C.
 Test Facility Harlan (2014a)

Water Extractability < 0.934 mg/g at 20 °C

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water.
 Remarks Flask Method. The water solubility was found to be < 1 × 10⁻³ g/L at 20 °C at the loading rate 1 g/L (extractability < 0.934 mg/g), and < 2.2 × 10⁻³ g/L at 20 °C at the loading rate 10 g/L (extractability < 0.218 mg/g).
 Test Facility Harlan (2014a)

Partition Coefficient (n-octanol/water) log Pow > 10

Method OECD TG 117 Partition Coefficient (n-octanol/water), High Performance Liquid Chromatography (HPLC) Method.
 Remarks HPLC Method. The column retention time for the test substance was longer than that for the standard (chemical) with the longest retention time.
 Test Facility Harlan (2014a)

Adsorption/Desorption log K_{oc} > 5.63
– main test

Method OECD TG 212 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
 Remarks HPLC Method. The column retention time for the test substance was longer than that for the standard (chemical) with the longest retention time.
 Test Facility Harlan (2014c)

Flash Point $192.3 \pm 2 \text{ }^{\circ}\text{C}$

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks Determined by closed cup equilibrium method
Test Facility Harlan (2014d)

Autoignition Temperature $372 \pm 5 \text{ }^{\circ}\text{C}$

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility Harlan (2014d)

Explosive Properties Not predicted to be explosive

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks Based on chemical structure of the test item
Test Facility Harlan (2014d)

Oxidizing Properties Not predicted to be oxidizing

Method EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks Based on chemical structure of the test item
Test Facility Harlan (2014d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified 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/Wistar
Vehicle	Arachis oil
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
Sighting test	1F	2000	0
Main test	4F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were observed.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed expected gains in body weight.

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY Harlan (2014e)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue 1
METHOD	Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/albino
Number of Animals	6
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	Scores were only recorded at 24 and 72 hours. The test substance was simultaneously applied to areas of abraded and intact skin on each animal.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Erythema/Eschar(intact skin)</i>	0.5	1	> 72 hours	1
<i>Erythema/Eschar(abraded skin)</i>	0.5	1	> 72 hours	1
<i>Oedema (intact skin)</i>	0	0	-	0
<i>Oedema (abraded skin)</i>	0	0	-	0

* Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Biosearch (1981a)

B.3. Irritation – eye

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/albino
Number of Animals	6
Observation Period	7 days
Remarks - Method	No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	0.8	1	< 5 days	0
<i>Conjunctiva: chemosis</i>	0.05	1	< 48 hours	0
<i>Conjunctiva: discharge</i>	0	0	-	0
<i>Corneal opacity</i>	0	0	-	0
<i>Iridial inflammation</i>	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Biosearch (1981b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	<i>Selenastrum capricornutum</i>
Exposure Period	72 hours
Concentration Range	Nominal: 10, 20, 40, 80, and 160 mg/L
Auxiliary Solvent	Not reported
Analytical Monitoring	Shimadzu TOC-V _{CPH} Total Organic Carbon (TOC) Analyser
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.
	The algae ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the notified polymer as it is a complex mixture and has low water solubility. WAFs of nominal loading rates were by stirring the test substance in prepared culture medium by using a magnetic stirrer for 23 hours followed by a 1-hour settlement period. WAF treatment solutions were separated from mixtures by mid-depth siphoning (a glass wool plug was attached to the opposite end of the tubing). Microscopic inspection of the WAFs showed no micro-dispersions or undissolved test tem to be present in the test solutions. All the exposure treatments (loading rates), except the loading rate of 20 mg/L, were observed to be clear and colourless.

RESULTS

Yield (72 h) (Filtered WAFs)		Growth (72 h) (Filtered WAFs)	
<i>E_b</i> L50 (mg/L)	<i>NOE_b</i> L (mg/L)	<i>E_r</i> L50 (mg/L)	<i>NOE_r</i> L (mg/L)
17	10	29	10

Remarks - Results	All validity criteria for the test were satisfied. The TOC concentrations of the WAFs were measured at 0 and 72 hours within the 72-h test period. The limit of quantification (LOQ) was determined to be 1.0 mg/L. The measured concentration values were approximately the LOQ. However, the endpoint values were calculated based on the nominal loading rates as the toxicity cannot be attributed to a single component or mixture of components but to the test substance as a whole. The Analysis of Variance (ANOVA) was used to calculate the end points.
CONCLUSION	The notified polymer is harmful to algae.
TEST FACILITY	Harlan (2014f)

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