File No: STD/1552

May 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Z-147

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
STD/1552	Lubrizol International Inc	Z-147	No	≤ 52 tonnes per annum	Component of metalworking fluids

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification 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).

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 safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin and eyes
  - Clean up spills promptly

- 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:
  - Gloves
  - Goggles
  - Protective clothing

  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

- 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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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(2) of the Act; if
- the function or use of the polymer has changed from component of metalworking 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of 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
Standard: Synthetic polymer with Mn < 1,000 Da (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, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, acute oral toxicity, acute dermal toxicity, dermal irritation, 28-day repeat dose toxicity, AMES, chromosome aberration and micronucleus tests

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-147

MOLECULAR WEIGHT
NAMW > 500 Da

ANALYTICAL DATA
Reference IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: viscous amber liquid

Property	Value	Data Source/Justification
Pour Point	9 ± 3 °C	Measured
Boiling Point	Decomposes from 302 °C at 100.2 kPa	Measured
Density	956 kg/m^3 at 20 ± 0.5 °C	Measured
Vapour Pressure	2.1 × 10^{-5} kPa at 25 °C	Measured
Water Solubility	< 1.3 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, the notified polymer is not expected to be hydrolysed under normal environmental conditions (pH 4 – 9).
Partition Coefficient	log Pow > 10	Measured

(n-octanol/water)		
Adsorption/Desorption	log Koc > 5.63	Measured
Dissociation Constant	Not determined	Contains ionisable functionality. Therefore, the notified polymer has potential to be ionised under normal environmental pH range of 4 – 9.
Particle Size	Not determined	Liquid
Flash Point	173 °C at 101.325 kPa	Measured
Autoignition Temperature	362 °C	Measured
Explosive Properties	Predicted negative	Contains no functional groups that would infer explosive properties
Oxidising Properties	Predicted negative	Contains no functional groups that would infer oxidising properties

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 is diluted with 20% mineral oil during manufacture and will be imported in this diluted form. The notified polymer may also be imported at < 1% in finished products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-15	10-15	22-28	48-52	48-52

PORT OF ENTRY
Western Australia, Queensland and Victoria

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 1 tonne steel containers. The steel containers containing the notified polymer will be transported by road or rail.

USE
The notified polymer will be used as a primary emulsifier component in soluble oil and semi-synthetic products for the metalworking industry, such as by automobile manufactures and automobile component/part manufactures and in fabricating other metal industrial products at < 1%.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. The notified polymer will be imported at 80% concentration and will be reformulated to a concentration of 5-8 wt% before being further diluted to < 1 wt% before use.

Reformulation
During reformulation, the imported product containing the notified polymer at up to 80% will be transferred from the imported containers into a blending tank. The containers will be opened by workers and connected to the blend vessels via direct lines and/or taps in the drum using quick connect fittings. The blending vessel is expected to be sealed and the notifier recommends that local exhaust ventilation is used. Quality assurance staff may take samples for analysis from a sampling port on the blending vessel. Once blending has been completed,

the finished product containing the notified polymer at 5-8% will be stored in sumps (ranging in size from 18,000 to 38,000 L) before it is sent to end users.

End use
At the end user site, the formulated product will be diluted with 90-95% water to make the metalworking fluid containing < 1% notified polymer. The fluid will be coated onto the metal surface and will move over the worked metal, cooling it and removing metal fragments produced during cutting etc. Excess fluid will drip down into the sump and be recirculated.

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 warehousing	0 - 2	100 - 225
Blending plant operators	0 - 2	100 - 225
Blending quality assurance (QA) staff	0 - 2	100 - 225
End-use plant operators	4 - 12	200

EXPOSURE DETAILS

Transport and storage
Transport and warehouse workers would only be exposed to the notified polymer in the event of an accident.

Reformulation
Dermal and ocular exposure to the notified polymer (up to 80% concentration) is possible when blending plant operators are connecting and disconnecting pump lines to storage tanks or blending vessels. The blending facilities are expected to be largely automatic and enclosed systems with ventilation and control systems in place for accidental spills and wastewater treatment. Dermal exposure (up to 80% concentration) is possible when cleaning up spills or leaks and during maintenance of the blending equipment. The use of personal protective equipment (PPE) such as coveralls, safety glasses, impervious gloves and respirators by the workers along with proper training in handling of the notified polymer as anticipated by the notifier and a high degree of automation should minimise the workers' exposure to the notified polymer.

As transfer of the finished lubricant containing the notified polymer at 5-8% concentration to packaging will be performed using possibly automated processes; exposure to workers is not expected. Inhalation exposure is expected to be low given the low vapour pressure of the notified polymer (2.1×10^{-5} kPa at 25 °C), unless aerosols or mists are generated.

Quality assurance sampling
At reformulation facilities samples will be taken from blending vessels for quality assurance testing. Dermal exposure to the notified polymer (up to 80% concentration) may occur during sampling. To minimise exposure, QA staff are expected to wear gloves, eye protection and long sleeved lab coats.

End use
Plant operators using the metalworking machinery and/or lathe units may come into contact with the notified polymer at 5-8% concentration. The exposure may occur during the manual transfer of the metalworking fluid concentrates from container into the make-up tank or during the cleaning and maintenance of equipment. The notifier anticipates that the processes will be mostly enclosed or supplied engineering controls such as shielding and local ventilation to reduce exposure from splashes, mists and vapours. The notifier states that exposure will be minimised by the use of personal protective equipment (PPE) such as gloves, goggles and protective clothing.

6.1.2. Public Exposure
The notified polymer and the products containing it are expected to be used in industrial settings only. Therefore, given the proposed use pattern, public exposure is not expected except in the event of accidental release.

6.2. Human Health Effects Assessment

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

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Analogue polymer	LD50 > 2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	Analogue polymer	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	Analogue polymer	slightly irritating
Rabbit, eye irritation	Notified polymer	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	Notified polymer	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28days	Analogue polymer	NOEL= 150 mg/kg bw/day (males) NOEL = 50 mg/kg bw/day (females) NOAEL = 150 mg/kg bw/day (both sexes)
Mutagenicity – bacterial reverse mutation	Analogue polymer	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	Analogue polymer	non genotoxic
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	Analogue polymer	non genotoxic

The analogue polymer is composed of one more monomer than the notified polymer. While the additional monomer may make the analogue polymer more irritating than the notified polymer, it was considered that the analogue polymer would have similar toxicological profiles for other human health endpoints as the notified polymer.

Toxicokinetics, metabolism and distribution
Absorption of the notified polymer across biological membranes is likely to be limited, based on the relatively high molecular weight (> 500 Da) and measured low water solubility. However, there are significant levels of low molecular weight species and the possibility of absorption cannot be ruled out.

Acute toxicity
Based on studies conducted in rats on the analogue polymer, the notified polymer was considered to have low acute oral and dermal toxicity.

Irritation
Based on studies conducted in rabbits using the analogue polymer and the notified polymer, the notified polymerwas considered to be slightly irritating to the skin and eyes.

Sensitisation
In a modified Buehler test using guinea pigs the notified polymer showed no evidence of skin sensitisation.

Repeated dose toxicity
A 28 day repeat dose study by oral gavage was conducted in rats with the analogue polymer at dose levels of 0, 50, 150 and 1,000 (then 500 from day 16) mg/kg bw/day. The No Observed Effect Level (NOEL) was established as 150 mg /kg bw/day for males and 50 mg /kg bw/day for females, based on toxicological significant changes observed at dose levels of 150 and 1,000 mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day for both sexes. Most of the findings were at least partially reversed following an additional 14 days without treatment.

Mutagenicity/Genotoxicity
The notified polymer was not considered to be mutagenic in a bacterial reverse mutation study and was not considered to be clastogenic in an *in vitro* mammalian chromosome aberration test or *in vivo* mammalian erythrocyte micronucleus test.

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification 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

Toxicological data available for the notified polymer or an acceptable analogue polymer showed that the notified polymer is slightly irritating to the skin and eyes.

Dermal, ocular exposure of workers to the notified polymer at concentrations of up to 80% may occur during transport, reformulation and end use. Exposure will be minimised by the use of automated and enclosed processes and PPE.

Workers may potentially be at risk of irritating effects to the skin and eyes from exposure when handling products containing the notified polymer at concentrations of 80%. Following reformulation the notified polymer is unlikely to be to be irritating due to the low concentration.

Provided the stated control measures are in place to limit exposure, the risk of the notified polymer to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer and the finished products containing it are intended for industrial applications only, hence public exposure is not expected. Therefore, the notified 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 notified polymer will not be manufactured in Australia. However, the notified polymer will be imported as a raw material for local reformulation. Blending is expected to take place in fully-contained industrial facilities. The potential for spills and leaks during transport, storage and blending are expected to be low. Spills of the waste metalworking fluids are expected to be contained within bunds and reclaimed or sent to a licensed waste collector.

RELEASE OF CHEMICAL FROM USE

The finished metalworking fluids containing the notified polymer will be used in closed systems at industrial sites. Waste trapping technology, such as catch pans and splash guards, will direct any losses back into the system for reuse. Therefore, release of the notified polymer to the environment via fugitive emissions is expected to be limited. The diluted metalworking fluid will be circulated through contained systems until they are spent.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues in empty containers and some of the collected spills are expected to be disposed of to landfill. In small facilities, spent metalworking fluids containing the notified polymer are expected to be drained, drummed off and disposed of to a liquid waste treatment facility. In large facilities, some waste handling is expected to be done on site, where the emulsion is split into the oil and water fractions by means of ultra filtration. The oil fraction is expected to be disposed of to a liquid waste treatment facility while the water-fraction is expected to be released to a sewage treatment system.

7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable based on the environmental fate study conducted on a close analogue. For the details of the environmental fate studies please refer to Appendix C. The notified polymer is not expected to partition significantly to the air compartment based on its low vapour pressure (2.1×10^{-2} kPa). The majority of the notified polymer is expected to be released to wastewater from discharge of spent metalworking fluids. Wastewater is expected to be collected and treated by a wastewater treatment facility before being released to the sewer. During treatment, the majority of the notified polymer is

expected to be removed due to its biodegradability (38% over a 28 day test period) and high log K_{oc} value (log K_{oc} > 5.6). The notified polymer, which is released to receiving waters, is expected to disperse and degrade. There is potential for bioaccumulation based on its high water/octanol partition coefficient (log Pow > 10). However, it is expected to have very limited bioavailability due to its very low water solubility. Sludge from wastewater treatment plans which may contain some of the notified polymer is expected to be disposed of to landfill or applied to agricultural soils.

Notified polymer in landfill or soil is not expected to be mobile based on its high soil adsorption coefficient (log Koc > 5.6). In landfill, soil and water, the notified polymer is expected to gradually degrade into water, and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Wastewater streams receiving the spent notified polymer may be directed to sewers. Therefore, under a worst case scenario, it is assumed that 100 % of the total import volume of the notified polymer will be discharged into sewers over 260 days per year corresponding to release only on working days. The predicted environmental concentration (PEC) can be estimated as outlined below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	52,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	52,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	200	kg/day
Water use	200.0	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:	44.22	µg/L
PEC - Ocean:	4.42	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 notified 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 44.2 µg/L may potentially result in a soil concentration of approximately 294.8 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 1.4 mg/kg and 2.9 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from 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 (96 h)	LL50 > 100 mg/L (WAF)	Not harmful to fish
Daphnia Toxicity (48 h)	EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrates

WAF: Water Accommodated Fraction

On the basis of the acute toxicity data, the notified polymer is not harmful to fish and aquatic invertebrates. Therefore, the notified polymer is not formally classified for either the acute or chronic toxicity under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009) due to a lack of aquatic toxicity.

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 lower endpoints for the test species (fish and daphnia, LL50/EL50) for the notified polymer. Two acute ecotoxicity endpoints for aquatic species from only two trophic levels are available. Therefore, an assessment factor of 1000 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Invertebrates).	100	mg/L
Assessment Factor	1,000	
PNEC:	100	µg/L

7.3. Environmental Risk Assessment

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

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	44.22	100	0.442
Q - Ocean:	4.42	100	0.044

The risk quotient for discharge containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its reported use pattern and annual importation quantity. The notified polymer has low water solubility, and high log Pow and log K_{oc} values. Therefore, the notified polymer is not expected to be significantly bioavilable in the aquatic environment. On the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point 9 ± 3 °C

Method OECD TG 102 Melting Point/Melting Range.
EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Test Facility Harlan (2014a)

Boiling Point Decompose from 302 °C at 100.2 kPa

Method OECD TG 103 Boiling Point.
EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks Differential scanning calorimetry was used.
Test Facility Harlan (2014a)

Density 956 kg/m^3 at 20.0 ± 0.5 °C

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

Vapour Pressure 2.1×10^{-5} kPa at 25 °C
6.5×10^{-4} kPa at 65 °C

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

Water Solubility $< 1.3 \times 10^{-4}$ g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method
Test Facility Harlan (2014a)

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

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC Method. The column retention time for the notified polymer was longer than that for the standard (a chemical) with the longest retention time.
Test Facility Harlan (2014a)

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

Method OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)
Remarks HPLC Method. The column retention time for the notified polymer was longer than that for the standard (a chemical) with the longest retention time.
Test Facility Harlan (2014c)

Flash Point 173 ± 2 °C at 101.325 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks A closed cup flash point tester was used.
Test Facility Harlan (2014c)

Autoignition Temperature 362 ± 5 °C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	Carbolite flask heater was used.
Test Facility	Harlan (2014c)

Explosive Properties Predicted negative

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

Oxidizing Properties Predicted negative

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

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Arachis oil B.P.
Remarks - Method	No protocol deviations. As there were no deaths or clinical signs of toxicity in the range finding study, a dose level of 2,000 mg/kg bw was selected for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1 (range-finding study)	1 per sex	2,000	0
2 (main study)	5 per sex	2,000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were observed during the main study.
Effects in Organs	No abnormalities were observed at necropsy.
Remarks - Results	Expected body weight gain was shown in all animals during the main study.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Safepharm (1995a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/Sprague-Dawley CD
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

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	Very slight or well-defined erythema was observed at the treatment sites of all female animals on removal of patches and persisted for 3 or 4 days after treatment. Crust formation was evident at one treatment site in one female animal 3 and 4 days after treatment. All treatment sites appeared normal 5 days after treatment. No dermal reactions were noted at the treatment sites of the male animals during the study.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed during the study.
Effects in Organs	No abnormalities were observed at necropsy.
Remarks - Results	Expected body weight gain was shown in all animals during the main study.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY Safepharm (1995b)

B.3. Irritation – skin

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 per sex
Vehicle None
Observation Period 7 days
Type of Dressing Semi-occlusive.
Remarks - Method No protocol deviations

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Erythema/Eschar	1	0.7	0.3	1	1	0.3	2	7 days	0**
Oedema	0	0	0	0	0	0	1	< 24 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**With desquamation (considered reversible by the study authors).

Remarks - Results Very slight to well-defined erythema was noted at all treated skin sites at the 1-hour observation with very slight erythema at the 24-hour observation. Very slight erythema was noted at four treated skin sites at the 48-hour observation and three treated skin sites at the 72-hour observation. Desquamation, which was considered by the study authors to be reversible, was noted for four treated skin sites at the 7-day observation.

Very slight oedema was noted at all treated skin sites at the 1-hour observation.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Safepharm (1995c)

B.4. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White
Number of Animals 2 F
Observation Period 7 days
Remarks - Method No protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2			
Conjunctiva: redness	2	2	2	< 7 days	0
Conjunctiva: chemosis	1	1.7	2	< 7 days	0

Conjunctiva: discharge	1	1	2	< 7 days	0
Corneal opacity	0	0	0	-	0
Iridial inflammation	0.7	0.3	1	< 72 hours	0

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

Remarks - Results

No corneal effects were observed during the study.

Iridial inflammation was observed in both treated eyes 1 and 24 hours after treatment and persisted in one treated eye at the 48-hour observation.

Moderate conjuctival irritation was observed in both treated eyes 1, 24 and 48 hours after treatment. Moderate conjunctival irritation persisted in one treated eye with minimal conjunctival irritation noted in the other treated at the 72-hour observation.

Both treated eyes were normal at the 7-day observation.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

Harlan (2014d)

B.5. Skin sensitisation

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 406 Skin Sensitisation - Modified Buehler.

Species/Strain

Guinea pig/Hartley-derived albino

PRELIMINARY STUDY

Maximum Non-irritating Concentration: 100%
topical: 0, 25, 50, 75 and 100%

MAIN STUDY

Number of Animals

Test Group: 10 per sex Control Group: 5 per sex

INDUCTION PHASE

Induction Concentration:
topical: 100%

Signs of Irritation

Slight patchy erythema was noted in four test animals, mainly at the 24 hour observation.

CHALLENGE PHASE

challenge

topical: 100%

Remarks - Method

The induction procedure was repeated on days 1, 7 and 14 so that a total of 3 consecutive induction exposures were made to the test animals.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	100%	2/20	2/20
Control Group	100%	2/10	0/10

Remarks - Results

There was no scheduled death. The body weight gain was normal.

Group mean dermal scores for the test substance animals were similar to the test and challenge control animals.

The results from positive control animals showed the test system was valid.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY Charles River (2014)

B.6. Repeat dose toxicity

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain Rat/Sprague-Dawley CD
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 Arachis oil BP
Remarks - Method No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	50	0
mid dose	5 per sex	150	0
high dose	5 per sex	1,000/500*	1 F
control recovery	5 per sex	0	0
mid dose recovery	5 per sex	150	0
high dose recovery	5 per sex	1,000/500*	0

*Due to one death at 1,000 mg/kg bw/day and a marked deterioration in health of remaining animals, the dosage was reduced to 500 mg/kg bw/day from day 16 onwards.

Mortality and Time to Death
One female dosed at 1,000 mg/kg bw/day was found dead at the beginning of day 12.

Clinical Observations
Animals of either sex dosed at 1,000 mg/kg bw/day showed clinical abnormalities from day 4 onwards and many of these animals underwent a sudden deterioration in conditions towards the end of week 2, showing increased salivation, fur wetting, red/brown staining, hunched posture, fur loss and tiptoe gait. Sporadic incidents of dehydration and diuresis might be attributed to the excessive fluid loss and increased water intake respectively. The incidence of a number of clinical abnormalities regressed after the dosage was halved, including the increased water consumption and incidence of prolonged increased salivation.

Animals of either sex dosed at 1,000 mg/kg bw/day showed a substantially reduced bodyweight gain during the first half of the treatment period with a reduced dietary intake and a reduced food efficiency, including three female animals showing no overall body weight gain during week 2 or a slight loss in bodyweight between days 7 and 14, and two of these animals being emaciated for several days midway through the treatment period. The adverse effect and the emaciation regressed after the dosage was halved, with animals of either sex showing a substantially greater food efficiency during the final week of the treatment period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Blood chemistry observations in animals of either sex dosed with 1,000 mg/kg bw/day included raised plasma enzyme levels (gamma glutamyltranspeptidase, aspartate aminotransferase, alanine aminotransferase and alkaline phosphatase) at the end of the treatment period and also increased plasma concentration of cholesterol and bilirubin. These blood chemical changes were considered by study authors to be associated with the morphological hepatic changes at this dose level and to be consistent with biliary obstruction. Clinical evidence of jaundice at this dose level was observed with pale/yellow extremities from day 12 onwards. This clinical abnormality regressed after several days without treatment. Other blood chemical and haematological changes identified at this dose level, such as a reduced total protein concentration, a reduced albumin concentration and a slightly increased clotting time, often accompany liver damage. However, increased anabolic activity associated with the marked increase in food efficiency and improvement in bodyweight development observed towards the end of treatment period might be explained by the reduced plasma total protein and albumin levels. The remaining treatment-related hepatic changes involved accumulation of pigment in the periportal region.

The pigment was identified, however, histological investigations showed the pigment was unlikely to be haemoglobin-derived because it was negative for Perl's stain.

Some of the treatment-related liver changes detected at the end of dosing period were reversible following the additional 14 days without treatment except that all female animals and one of the male animals dosed at 1,000 mg/kg bw/day showed gross hepatic lesions at necropsy on day 43. Histological lesions showed partial regression by the end of the recovery period and the severity of bile duct proliferation among animals of either sex was reduced compared with what was observed at the end of dosing period. Periportal stromal fibrosis also regressed among the male animals but not among the female animals and there was no regression of pigment accumulation in the periportal region of the liver following the recovery period. In addition, relative liver weight (relative to terminal bodyweight) remained slightly elevated among animals of either sex, though the residual effect among the male animals was less convincing than among the female animals.

Haematological investigations showed changes among animals of either sex dosed at 1,000 mg/kg bw/day consistent with an anaemia. This effect was considered by study authors not to be haemolytic in nature due to the absence of any haemosiderin pigment deposition. High dose animals of either sex showed slightly elevated reticulocyte count and a macrocytosis was identified for female animals, which showed a marginally increased mean corpuscular volume (MCV) and a reduced mean corpuscular haemoglobin concentration. Macrocytic anaemias were considered by study authors to link with possible liver damage, in which case they developed independent of deficiency in vitamin B_{12} or folic acid. The clinical observation of pale extremities, which were evident from day 12 of treatment, was attributed by study authors to jaundice, however, it could also be associated with these haematological abnormalities. Spleen weight was increased at the end of dosing period, especially for the female animals, however, this finding was considered unlikely to be associated with the haematological changes as histological changes in the spleen were confined to deposition of a non-haemoglobin-derived granular pigment. In addition, there was no evidence of a treatment-induced change in splenic extramedullary haemopoiesis.

At the end of recovery period, the residual anaemia was not obvious despite MCV remaining marginally elevated for the female animals. Animals also did not show pale/yellow extremities within 4 days of stopping treatment.

Effects in Organs

Liver changes such as an increased liver weight at the end of the treatment period and gross hepatic lesions observed for most animals survived to necropsy on day 29, were detected at the end of treatment period and also following the recovery period of 14 days among animals of either sex dosed at 1,000 mg/kg bw/day.

Absolute and relative spleen weight remained elevated following recovery for the female animals dosed at 1,000 mg/kg bw/day and histological examination of the spleen identified deposits of granular pigment for animals of either sex.

Kidney changes were observed in animals of either sex dosed at 1,000 mg/kg bw/day. Male animals showed a slightly increased relative kidney weight at the end of dosing period and histological examination showed accumulation of pigment in the tubular epithelium. Despite diuresis observed in three male animals, there was no convincing evidence of renal dysfunction. Histological examinations at the end of recovery period identified deposits of pigment in the renal tubular epithelium for 4 female animals at a slightly reduced severity compared with what was seen at the end of the dosing period. Renal changes were completely reversed for all male animals after the recovery period.

Toxicologically significant changes at a dose level of 150 mg/kg bw/day was confined to one female animal which showed bile duct proliferation (graded minimal) at the end of dosing period and the changes were not detected following 14-day recovery period.

Remarks – Results

A number of toxicologically significant changes were observed at a dose level of 1,000 mg/kg bw/day and there was minimal bile duct proliferation for one female animal dose at 150 mg/kg bw/day. Most of the treatment-related effects were reversible after an additional 14 days without treatment although several toxicologically significant changes, especially those involving the liver, were still present at the end of the recovery period among animals dosed at 1,000 mg/kg bw/day.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 150 mg/kg bw/day for males and 50 mg/kg bw/day for females in this study, based on the absence of toxicologically significant changes among male animals dosed at 150 mg/kg bw/day or among animals of either sex dosed at 50 mg/kg bw/day.

The No Observed Adverse Effect Level (NOAEL) was established as 150 mg/kg bw/day in both males and females based on the fact that the bile duct formation in females treated with 150 mg/kg bw/day was observed in only one animal and was of minimal severity.

TEST FACILITY Safepharm (1996a)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
Vehicle	Acetone
Remarks - Method	No protocol deviations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5,000			
Test 1		≥ 150	> 5,000	negative
Test 2		≥ 150	> 5,000	negative
Present	> 5,000			
Test 1		≥ 50	> 5,000	negative
Test 2		≥ 500	> 5,000	negative

Remarks - Results

No toxicity to the bacterial background lawn was exhibited to any of the strains of bacteria used, although small and inconsistent decreases in revertant colony frequency were observed (mainly in the TA1535 and TA1537 strains).

No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains with any dose of the test substance either with or without metabolic activation.

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

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Safepharm (1996b)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Analogue polymer

METHOD Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line Chinese hamster lung (CHL) cells

Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	No protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 1.25, 2.5, 5, 10*, 20*, 40*	12	12
Test 2a	0*, 4.88, 9.75*, 19.5*, 39*, 58.55	24	24
Test 2b	0*, 4.88*, 9.75*, 19.5*, 39, 58.55	48	48
Test 2c	0*, 4.88, 9.75, 19.5*, 39*, 58.55*	6	24
Test 2d	0*, 5, 10*, 20*, 40*, 60, 80	12	12
Present			
Test 1	0*, 5, 10, 20, 40*, 80*, 160*	4	12
Test 2a	0*, 9.75, 19.5, 39*, 78.1*, 117.2*	6	24
Test 2b	0*, 20, 40*, 80*, 160*, 240, 320	4	12

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 40	> 40	negative
Test 2a	> 58.55	> 58.55	negative
Test 2b	≥ 39	> 58.55	negative
Test 2c	> 58.55	> 58.55	negative
Test 2d	≥ 40	> 80	negative
Present			
Test 1	> 160	> 160	negative
Test 2a	> 117.2	> 117.2	negative
Test 2b	≥ 160	> 320	negative

Remarks - Results

The mitotic indices generally gave a measure of toxicity greater than that indicated by the cell counts

The vehicle control and positive control cultures gave values of chromosome aberrations within the expected range, indicating that the metabolic activation system and test method were satisfactory. It was considered by study authors that the poor response observed for the positive control was due to toxicity-induced cell-cycle delay.
The test substance induced no toxicologically significant dose-related increases in the frequency of cells with aberrations.

CONCLUSION

The test substance was not clastogenic to CHL cells treated in vitro under the conditions of the test.

TEST FACILITY

Safepharm (1996c)

B.9. Genotoxicity – in vivo

TEST SUBSTANCE

Analogue polymer

METHOD

EC Directive 92/69/EEC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain	Mice/albino CD-1
Route of Administration	Intraperitoneal administration
Vehicle	Arachis oil
Remarks - Method	No protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	24
			48
II (low dose)	5 per sex	37.5	24
			48
III (mid dose)	5 per sex	75	24
			48
IV (high dose)	5 per sex	150	24
			48
V (positive control, CP)	5 per sex	50	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity

No mortality or clinical signs were observed in any of the treatment groups of the main study.

Genotoxic Effects

The presence of clinical signs and premature deaths in the range-finding toxicity study indicated that systemic absorption occurred. The steep toxicity curve observed in the range-finding study resulted in the selection of a maximum tolerated dose level that was expected to produce clinical signs in the main study.

No significant increase in the frequency of micronucleated PCEs and no statistically significant change in the PCE/NCE ratio in any of the test substance dose groups compared to the concurrent vehicle control groups was observed. The absence of clinical signs in the main study was considered by study authors not to affect its integrity or validity.

Remarks - Results

The positive control induced a statistically significant increase in the incidence of microcleated PCEs in both male and female mice. The number of micronucleated PCEs in the vehicle control groups did not exceed the historical vehicle control range. Based upon this, the test was considered valid.

There is no definitive evidence indicating that the test substance reached the bone marrow of the mice.

CONCLUSION

The test substance was not clastogenic under the conditions of this *in vivo* Mammalian Erythrocyte Micronucleus Test.

TEST FACILITY

Safepharm (1995d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Lonics 155B and Dohrmann DC 190 Carbon analysers for dissolved organic carbon (DOC) and total organic carbon (TOC), and HPLC for residual substance concentration.
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	25	7	51
14	29	14	65
21	34	21	Not reported
28	38	28	79

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, aniline, reached the 60% pass level by day 14 indicating the suitability of the inoculum. The degree of degradation of the notified polymer after the cultivation period was 38%. Therefore, the test substance is classified as not readily biodegradable according to the OECD (301 C) guideline.
CONCLUSION	The analogue and, by inference, the notified polymer are not readily biodegradable.
TEST FACILITY	Safepharm (1996d)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	Semi-static- Fish, Acute Toxicity Test OECD TG 203
Species	Rainbow trout *(Oncorhynchus mykiss)*
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC - MS
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 fish ecotoxicity test was conducted in a Water Accommodated Fraction (WAF) of the notified polymer as it is a complex mixture and has low water solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water for 23 hours followed by a 1-hour settlement period. Then, the WAF solution was filtered through a glass wool plug. The exposure treatment (loading rate) was observed to be clear and colourless.

RESULTS

Nominal Concentration (WAF; mg/L)	*Number of Fish*	*Accumulative Mortality (%)*				
		3h	*24h*	*48h*	*72h*	*96h*
Control	7	0	0	0	0	0
100	7	0	0	0	0	0

LL50	> 100 mg/L at 96 hours (WAF)
NOEL	100 mg/L at 96 hours(WAF)
Remarks – Results	All validity criteria for the test were satisfied. The test was conducted as a limit test. The 96-hour LL50 was determined by visual observation. Chemical analyses of the WAF solutions at 0 and 72 hour (fresh media) and the 24 and 96 hours (old media) showed measured test concentrations of less than the limit of quantification (LOQ) of the analytical method, which was 0.0039 mg/L. However, median lethal loading rate (LL50) and no observed effect loading rate (NOEL) 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.
CONCLUSION	The notified polymer is not harmful to fish.
TEST FACILITY	Harlan (2014e)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC - MS
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 daphnia ecotoxicity test was conducted in a Water Accommodated Fraction (WAF) of the notified polymer as it is a complex mixture and has low water solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water for 23 hours followed by a 1-hour settlement period. Then, the WAF solution was filtered through a glass wool plug. The exposure treatment (loading rate) was observed to be clear and colourless.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of D. magna*	*Cumulative % Immobilised*	
		24 h	*48 h*
Control	20	0	0
100	20	0	0

EL50	> 100 mg/L at 96 hours (WAF)
NOEL	100 mg/L at 96 hours(WAF)
Remarks - Results	All validity criteria for the test were satisfied. The test was conducted as a limit test. The 48-hour EL50 was determined by visual observation. Measured concentrations of the WAF solutions at 0 and 48 hour were 0.62 and 0.49 mg/L, respectively. However, median lethal loading rate (LL50) and no observed effect loading rat e (NOEL) 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.
CONCLUSION	The notified polymer is not harmful to aquatic invertebrates.
TEST FACILITY	Harlan (2014f)

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