

File No: LTD/1754

August 2014

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

PUBLIC REPORT

Polymer in OLI 9000.m

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/1754	A S Harrison & Co Limited	Polymer in OLI 9000.m	ND	≤ 100 tonnes per annum	Fuel Additive

*ND = not determined

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 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

CONTROL MEASURES

Occupational Health and Safety

- 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 should be disposed of to landfill.

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 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 an additive in diesel fuels 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 a product containing the notified polymer was 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)

A & S Harrison & Co Limited (ABN: 89 000 030 437)
75 Old Pittwater Road
BROOKEVALE NSW 2100

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, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, and additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: partition coefficient, adsorption/desorption, dissociation constant, hydrolysis as a function of pH and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2005)
Canada (2005)
China (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

OLI 9000.m (product containing the notified polymer at ~70% concentration)

CAS NUMBER

Not assigned

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 98%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer is not expected to undergo loss of monomers, reactants, additives or impurities under the normal condition of use and storage.

DEGRADATION PRODUCTS

The notified polymer is not expected to degrade under normal conditions of storage and transport. However, under normal conditions of use as a fuel additive, the polymer is expected to degrade (via aspirated combustion) into oxides of carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-24.8 °C	Measured
Boiling Point	293.4 °C at 101.3 kPa	Measured
Density	1004.3 kg/m ³ at 20 °C	Measured
Vapour Pressure	2.3 x 10 ⁻⁷ kPa at 25 °C	Measured
Water Solubility	≤ 3 x 10 ⁻³ g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains functional groups that are expected to hydrolyse very slowly in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the octanol phase from water based on the mainly hydrophobic structure
Surface Tension	34.75 mN/m	Measured
Adsorption/Desorption	Not determined	Expected to adsorb to soil or sediment sludge based on the mainly hydrophobic structure
Dissociation Constant	Not determined	The notified polymer does not contain dissociable functional groups
Flash Point	158.5 °C (closed cup)	Measured
Flammability	Not expected to be flammable	Based on measured flash point and auto-ignition temperature
Autoignition Temperature	380 °C	Measured
Explosive Properties	Not expected to be explosive	Estimated based on chemical structure
Oxidising Properties	Not expected to be oxidising	Estimated based on chemical structure

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 as a component of fuel additive packages at < 3% 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

Melbourne, Sydney and Perth

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as part of diesel fuel additive packages contained in 2.5, 28 and 200 L drums or 10,000 L intermediate bulk containers (IBC).

USE

The notified polymer will be used as a fuel additive at up to 0.01% concentration.

OPERATION DESCRIPTION

The additive package (which contains the polymer at < 3% concentration) will be added to the fuel at the refinery and/or fuel distribution terminal, prior to the transport of the fuel to retail stations. The additive package will typically be added to the fuel either by continuous injection into a fuel line or by batch addition of the notified polymer into a fuel storage tank, at up to 0.01% concentration.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	3	6 - 8
Formulator	2	6 - 8
Quality Control Analysis	2	6 - 8
Transport and use of fuel	10 - 20	6 - 8

EXPOSURE DETAILS

The potential routes of occupational exposure are dermal and ocular. Inhalation exposure is not expected as the polymer has a low vapour pressure and the generation of mists or aerosols is not expected.

Transport and storage

Transport workers are not expected to be exposed to the imported product containing the notified polymer at < 3% concentration, as they will be handling closed containers. Dermal or ocular exposure is possible in the event of an accident where the packaging is breached or during transfer to storage tanks.

Blending

At the fuel manufacturer's refinery terminal, blending of the notified polymer with refined fuel will be carried out automatically or semi-automatically in a closed system, usually through metering into tank trucks. Exposure to the notified polymer may occur from accidental spillage. Exposure is expected to be low and further reduced by workers wearing personal protective equipment when handling fuel.

Worker exposure to the notified polymer at up to 3% concentration may also occur during sampling and analysis of blended fuel at the refinery or during maintenance of refinery plant or pipelines. The exposure would be limited by appropriate personal protective equipment worn by workers

Transport and storage of fuel

Dermal or ocular exposure to drips and spills of fuel containing the notified polymer at up to 0.01% concentration is possible during the connection and disconnection of transfer hoses. Exposure is expected to be limited during transportation as the protocols of loading and unloading are done with minimal spills. The drivers also usually wear gloves and long sleeve shirts when unloading the fuel

End users of fuel

Personnel from commercial trucking fleet, users of off road vehicles and users of agriculture equipment may be exposed to fuel containing the notified polymer at up to 0.01% concentration during handling and fuelling of the vehicles.

6.1.2. Public Exposure

The public will not have exposure to the imported product containing the notified polymer at < 3% concentration as it will be used in industrial settings.

The public may have incidental skin or eye contact with fuel containing the notified polymer at up to 0.01% concentration through operations such as refilling vehicles.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and an acceptable analogue 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 ¹	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation ¹	slightly irritating
Rabbit, eye irritation ¹	slightly irritating
Guinea pig, skin sensitisation – adjuvant test ²	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation ³	non mutagenic

¹Test substance: Analogue at 70% concentration

²Test substance: Analogue at 90% concentration

³Test substance: Notified polymer

Toxicokinetics.

Based on the use pattern, the main exposure route is expected to be dermal. Given the high molecular weight (> 1,000 Da), low water solubility and low percentage of molecular weight species < 500 Da, the dermal absorption potential is expected to be limited

Acute toxicity.

The analogue polymer at 70% concentration is of low acute oral toxicity in rats.

Irritation and sensitisation.

The analogue polymer at 70% concentration is slightly irritating to the eye and skin of rabbits. In the skin irritation study, slight irritation was observed in all animals at the 24-hour observation period that was resolved at the 48-hour observation period. In the eye irritation study, slight to moderate conjunctival irritation was observed in all animals that persisted up to the 4-day observation period. All animals showed full recovery 7 days after exposure.

The analogue polymer showed no evidence of sensitisation in a Guinea Pig maximisation test at a challenge concentration of 90%.

Mutagenicity/Genotoxicity.

The notified polymer was not mutagenic in a bacterial reverse mutation test with or without metabolic activation.

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

Based on the available information, the notified polymer is expected to be of low hazard presenting only as a slight skin and eye irritant.

Workers may be exposed to the notified polymer at < 3% concentration. At these low use concentrations irritation effects are not expected. Therefore, the risk to workers from use of the notified polymer as described is not expected to be unreasonable.

6.3.2. Public Health

Based on the available information, the notified polymer is expected to be of low hazard presenting only as a slight skin and eye irritant.

The public may be exposed to the notified polymer at < 0.01% concentration in fuel. Given the low use concentration and expected low hazard of the notified polymer, the risk to the public from the use of the notified polymer is not expected 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 fuel additive packages and is expected to be blended with fuels at industrial facilities in Australia. Blending sites such as fuel refineries are expected to have cleaning and disposal procedures compliant to industry standards. Thus, release to the aquatic environment is unlikely during blending activities. Environmental release during importation, reformulation, transport and distribution may occur as a result of accidental spills. The container filling processes are computer automated, so minimal spills due to loading are expected. In the event of a spill, the notified polymer should be contained, collected and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The fuels containing the notified polymer are expected to be available at retail fuel outlets. The notified polymer is consumed during the combustion of the fuel to generate primarily water and oxides of carbon.

RELEASE OF CHEMICAL FROM DISPOSAL

Import containers, such as ISO tanks, IBCs and drums, are anticipated to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an on-site waste treatment facility and any waste sludge is likely to be sent to landfill.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable. For the details of the environmental fate studies please refer to Appendix C. Low molecular weight species of the notified polymer may bioaccumulate based on their hydrophobic property. This is not considered to be a concern since no significant release to the environment is expected based on the proposed use pattern. Most of the notified polymer in fuel will be consumed and degraded during use. Minor amounts of the notified polymer are expected to be released to landfill as residues in containers or treatment wastes. In landfill, the notified polymer is not expected to be mobile due to its low water solubility. The notified polymer is expected to degrade by slow biotic and abiotic processes in landfill, or by thermal decomposition during use, to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern.

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.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	48 h EL50 > 100 mg/L	Not harmful
Algal Toxicity	72 h E _r L50 > 160 mg/L	Not harmful
	72 h NOEC = 160 mg/L	

Based on the above endpoints, the notified polymer is not considered to be harmful to *Daphnia* and alga up to the limit of its water solubility. Based on the toxicity to aquatic biota the notified polymer is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) on acute and chronic bases.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as it is not harmful to aquatic organisms up to the limit of its water solubility.

7.3. Environmental Risk Assessment

Calculation of the Risk Quotient (PEC/PNEC) is not possible since neither the PEC nor the PNEC is available. The majority of the notified polymer will be thermally decomposed during its use as an additive in fuels. Exposure to the aquatic compartment is unlikely based on the reported use pattern. On the basis of its assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** -24.8 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks Determined using Differential scanning calorimetry (DSC)
Test Facility Innospec (2010a)

Boiling Point 293.4 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
Remarks Determined using Differential scanning calorimetry (DSC)
Test Facility Innospec (2010b)

Density 1004.3 kg/m³ at 20 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Determined using Parr density meter
Test Facility Innospec (2009)

Vapour Pressure 2.3 x 10⁻⁷ kPa at 25 °C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks Determined using a vapour pressure balance
Test Facility Harlan (2008)

Water Solubility ≤ 3 x 10⁻³ g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Column Elution Method. The test substance was reported as OLI9000.m, which was a product containing the notified polymer. This is considered acceptable since the test substance preparation for the column method is expected to remove any liquid medium before determination of the solubility. The determined water solubility of 3 mg/L was reported for the test substance. The water solubility for the notified polymer it is not expected to be higher than the determined ≤ 3 mg/L based on the nature of the column test.
Test Facility Innospec (2010c)

Surface Tension 34.75 mN/m

Method OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks Concentration: Neat
Test Facility Innospec (2009)

Flash Point 158.5 °C (pressure unknown)

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks Pensky-Martins closed cup flash point apparatus was used.
Test Facility Innospec (2010d)

Autoignition Temperature 380 ± 5 °C

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

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Analogue polymer (70% concentration)
METHOD	EC Directive 92/69/EEC B.1bis Acute Toxicity (Oral) Fixed Dose Method.
Species/Strain	Rat/Sprague-Dawley
Vehicle	1% w/v aqueous methylcellulose
Remarks - Method	Composition of test substance was 70% analogue polymer and 30% polyisobutylene. No protocol deviations.

RESULTS

Sighting Study

<i>Dose mg/kg bw</i>	<i>Administered</i>	<i>Evident Toxicity</i>	<i>Mortality</i>
2000	1 F	None	0
500	1 F	None	0

Signs of Toxicity
Effects in Organs

Not provided in study report
Not provided in study report

Main Study

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	10 (5 M, 5 F)	2000	0

Discriminating Dose
Signs of Toxicity
Effects in Organs
Remarks - Results

2000 mg/kg bw
No signs of systemic toxicity.
No abnormalities were noted at necropsy.
In all animals, piloerection was observed within five minutes of dosing and persisted through to Day 3. No other clinical signs observed and recovery was complete by Day 4. All animals showed expected gains in bodyweight.

CONCLUSION

The test substance is of low toxicity via the oral route.

TEST FACILITY

Huntingdon Life Sciences (1996)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue polymer (70% concentration)
METHOD	EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M, 2 F)
Vehicle	None
Observation Period	3 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Composition of test substance was 70% analogue polymer and 30% polyisobutylene. No protocol deviations. Exposure period for all animals was 4 hours.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0.3	0.3	0.3	1	< 48 h	0
<i>Oedema</i>	0	0	0.3	1	< 48 h	0

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

Remarks - Results After 24 hours, all animals exhibited very slight erythema, with one animal exhibiting very slight oedema as well. Full recovery was observed in all animals 48 hours after exposure. No signs of toxicity or ill health was observed in any of the animals.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Huntingdon Life Sciences (1996)

B.3. Irritation – eye

TEST SUBSTANCE Analogue polymer (70% concentration)

METHOD EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals 3 (1 M, 2 F)

Observation Period 7 days

Remarks - Method Composition of test substance was 70% analogue polymer and 30% polyisobutylene. Conjunctiva discharge was not recorded in the study. There were no other protocol deviations. One animal was initially treated to check severity of response. Observations were taken at 1, 24, 48 and 72 hours, and 4 and 7 days post-exposure.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	1.3	1	1	2	< 7 days	0
<i>Conjunctiva: chemosis</i>	0.7	1	0	1	< 7 days	0
<i>Corneal opacity</i>	0	0	0	0	NA	0
<i>Iridial inflammation</i>	0	0	0	0	NA	0

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

Remarks - Results No corneal or iridial inflammation was observed. A diffuse crimson colouration of the conjunctivae with eyelid swelling was observed for two animals (1 hour after exposure), with the effects maintained in one after 24 hours, and full recovery from eyelid swelling in the other. All animals exhibited hyperaemic vessels for at least 4 days. Eyelid swelling was observed for 48 hours in one animal and up to 4 days in another. All animals showed full recovery 7 days after exposure. No other signs of toxicity or ill health was observed in any of the animals.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Huntingdon Life Sciences (1996)

B.4. Skin sensitisation

TEST SUBSTANCE	Analogue polymer (90% concentration)	
METHOD	EC Directive 96/54/EC B.6 Skin Sensitisation – Magnusson and Kligman	
Species/Strain	Guinea pig/Dunkin/Hartley	
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%	
MAIN STUDY		
Number of Animals	Test Group: 10	Control Group: 5
INDUCTION PHASE	Induction Concentration: Intradermal: 30% w/v in Alembicol D Topical: 100%	
Signs of Irritation	Intradermal injections: necrosis was observed at sites receiving Freund's Complete Adjuvant in test and control animals. Slight irritation was seen in test animals at sites receiving the analogue polymer 30% w/v in Alembicol D and slight irritation was observed in control animals receiving Alembicol D. Topical application: Slight erythema was observed in test animals following topical application with the test substance as supplied. Slight erythema was also seen in the control animals.	
CHALLENGE PHASE		
1 st challenge	Topical: 100% and 50% w/v in Alembicol D	
2 nd challenge	Not conducted	
Remarks - Method	Composition of test substance was 90% analogue polymer and 10% polyisobutylene. Six days after the injections all animals were treated with 10% sodium lauryl sulphate in petrolatum.	

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after:</i>			
		<i>1st challenge</i>		<i>2nd challenge</i>	
		<i>24 h</i>	<i>48 h</i>	<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	100%	0	0	-	-
	50%	0	0	-	-
<i>Control Group</i>	100%	0	0	-	-
	50%	0	0	-	-

Remarks - Results No signs of ill health or toxicity were recorded. All animals recorded an increase in bodyweight over the period of the study.

Challenge: No dermal reactions were seen in any of the test or control animals.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY Huntingdon Life Sciences (1996)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure.
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA ⁻
Metabolic Activation System	S9 mix from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50 - 5000 µg/plate b) Without metabolic activation: 50 - 5000 µg/plate
Vehicle	Dimethyl sulphoxide.
Remarks - Method	No protocol deviation.

RESULTS

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

*Slight, greasy film observed at 5,000 µg/plate

Remarks - Results	<p>In the preliminary toxicity test, the test material was not toxic to the bacterial background lawns of the bacteria used (TA100 and WP2uvrA⁻). However, TA100 exhibited decreases in revertant colony frequency at the maximum concentrations of the test material.</p> <p>The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level and was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. However, several strains exhibited decreases in revertant colony frequency. A slight, greasy film was observed at 5000 µg/plate, this observation did not prevent the scoring of revertant colonies.</p> <p>No significant increases in the frequency of revertant colonies were recorded for any of the strains of bacteria, at any dose level either with or without metabolic activation.</p> <p>All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.</p>
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan Laboratories Ltd (2009a)

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			
Inoculum	Activated sludge			
Exposure Period	28 days			
Auxiliary Solvent	Not applied			
Analytical Monitoring	CO ₂ evolution was measured for determination of biodegradation			
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP). The test substance was adsorbed onto the surface of granular silica gel. The test was conducted at a concentration of 10 mg carbon/L.			
RESULTS				
	<i>Test substance</i>		<i>Sodium benzoate</i>	
	<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
	2	7	10	66
	29	8	29	89
Remarks - Results	All the test validity criteria were met. The degradation in the control containing the notified polymer and reference substance (sodium benzoate) achieved 40% by day 29. Therefore, the notified polymer is not considered to be toxic to the micro-organisms. The notified polymer is not considered to be readily biodegradable based on the test result.			
CONCLUSION	The notified polymer is not readily biodegradable			
TEST FACILITY	Harlan (2009b)			

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer			
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test – Static test. EC Council Regulation No 440/2008 C.2 Acute Toxicity for <i>Daphnia</i> – Static test.			
Species	<i>Daphnia magna</i>			
Exposure Period	48 hours			
Auxiliary Solvent	Not applied			
Water Hardness	250 mg CaCO ₃ /L			
Analytical Monitoring	Test concentrations were determined using high performance liquid chromatography-mass spectrometry (HPLC-MS)			
Remarks - Method	The test was conducted following the test guideline and good laboratory practice (GLP).			
	Following a rang-finding test, a limit test was conducted using water accommodated fraction (WAF) at a loading rate of 100 mg/L. After addition of the notified polymer into the reconstituted water, the mixture was stirred 23 hours by magnetic stirrer. After the stirring, the mixture was allowed to stand for 1 hour. A wide bore glass tube, covered at one end with Nescofilm was submerged into the vessel, sealed end down, to a depth			

of approximately 5 cm from the bottom of the vessel. A length of Tygon tubing was inserted into the glass tube and pushed through the Nescofilm seal. A glass wool plug was inserted into the opposite end of the tubing and the WAF removed by mid-depth siphoning (the first 75 - 100 ml discarded) to give the 100 mg/L loading rate WAF. Microscopic observations were performed on the WAFs after filtering and showed micro-dispersions or undissolved test material present.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
0 (control)	0	20	0	0
100	0.74-1.1	20	0	0

EL50 > 100 mg/L at 48 hours

NOEL 100 mg/L at 48 hours

Remarks - Results

All the test validity criteria were met. Chemical analysis of the test preparations at 0 and 48 hours showed measured concentrations to range from 0.74 to 1.1 mg/L. Since no effects were observed in the test, the notified polymer is considered not to be harmful to *Daphnia* up to the limit of its water solubility.

CONCLUSION

The notified polymer is not harmful to *Daphnia*

TEST FACILITY

Harlan (2009c)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 201 Alga, Growth Inhibition Test.

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

Species *Desmodesmus subspicatus*

Exposure Period 72 hours

Concentration Range
Nominal: 10, 20, 40, 80, 160 mg/L
Actual: 0.026, 0.074, 0.048, 0.060 and 0.040 mg/L at 0 hour and 0.019, 0.044, 0.013, 0.0060 and 0.013 mg/L at 72 hour

Auxiliary Solvent Not applied

Water Hardness Not provided

Analytical Monitoring Test concentrations were determined using high performance liquid chromatography-mass spectrometry (HPLC-MS)

Remarks - Method The test was conducted following the test guideline and good laboratory practice (GLP).

Following a rang-finding test, a definitive test was conducted using water accommodated fractions (WAFs) at 5 loading rates. After addition of the notified polymer into certain volumes of the reconstituted water, the mixtures were each stirred 23 hours by magnetic stirrer. After the stirring, each of the mixtures was allowed to stand for 1 hour. A wide bore glass tube, covered at one end with Nescofilm was submerged into the vessel, sealed end down, to a depth of approximately 5 cm from the bottom of the vessel. A length of Tygon tubing was inserted into the glass tube and pushed through the Nescofilm seal. A glass wool plug was inserted into the opposite end of the tubing and the WAF removed by mid-depth siphoning (the first 75 - 100 ml discarded) to give the target loading rate WAF. Microscopic observations were performed on the WAFs after filtering and showed micro-dispersions or undissolved test material present.

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>E_bL50</i> mg/L at 72 h (WAF)	<i>NOEL</i> mg/L (WAF)	<i>E_rL50</i> mg/L at 72h (WAF)	<i>NOEL</i> mg/L (WAF)
> 160	160	> 160	160
Remarks - Results		<p>All the test validity criteria were met. The study author explained the concentration decline was in line with the preliminary stability analyses conducted which indicated that the test material was unstable over the test period. The results of the preliminary stability analyses showed that a similar decline in measured test concentrations was observed in samples stored in both light and dark conditions which would suggest that the observed instability was due to a media effect. No further information regarding the unstable property or degradates was provided. The notified polymer is not considered to have any functional groups that are readily hydrolysable. The biodegradability test indicates that the notified polymer is not readily biodegradable. Therefore, the decline in concentration over time may be from association of the notified polymer to container walls, instead of degradation.</p> <p>The notified polymer is not considered to be harmful to alga up to the limit of water solubility based on the test outcome.</p>	
CONCLUSION		The notified polymer is not harmful to alga	
TEST FACILITY		Harlan (2009d)	

BIBLIOGRAPHY

- Huntingdon Life Sciences (1996a) [analogue polymer]: Acute Oral Toxicity to the Rat (Project Number AOC 51/961797/AC, 3 September, 1996). Cambridgeshire, England, Huntingdon Life Sciences Limited (Unpublished report submitted by the Owner).
- Huntingdon Life Sciences (1996b) [analogue polymer]: Skin Irritation to the Rabbit (Project Number AOC 52/961927/SE, 22 August, 1996). Cambridgeshire, England, Huntingdon Life Sciences Limited (Unpublished report submitted by the Owner).
- Huntingdon Life Sciences (1996c) [analogue polymer]: Eye Irritation to the Rabbit (Project Number AOC 53/961931/SE, 22 August, 1996). Cambridgeshire, England, Huntingdon Life Sciences Limited (Unpublished report submitted by the Owner).
- Huntingdon Life Sciences (1996d) [analogue polymer]: Skin Sensitisation in the Guinea Pig (Project Number AOC 53/961931/SE, 5 November, 1996). Cambridgeshire, England, Huntingdon Life Sciences Limited (Unpublished report submitted by the Owner).
- Harlan (2008) Determination of Vapour Pressure and Auto-Ignition Temperature (Project Number 1608/0022, December, 2008). Derbyshire, United Kingdom, Harlan Laboratories Limited (Unpublished report submitted by the Owner).
- Harlan (2009a) Reverse Mutation Assay “Ames test” Using *Salmonella typhimurium* and *Escherichia coli* (Project Number 1608/0017, January, 2009). Derbyshire, United Kingdom, Harlan Laboratories Limited (Unpublished report submitted by the Owner).
- Harlan (2009b) Notified polymer: Assessment of Ready Biodegradability; CO₂ Evolution Test (Project Number 1608/0020, April, 2009). Derbyshire, United Kingdom, Harlan Laboratories Limited (Unpublished report submitted by the Owner).
- Harlan (2009c) Notified polymer: Acute Toxicity to *Daphnia magna* (Project Number 1608/0018, May, 2009). Derbyshire, United Kingdom, Harlan Laboratories Limited (Unpublished report submitted by the Owner).
- Harlan (2009d) Notified polymer: Algal Growth Inhibition Test (Project Number 1608/0019, May, 2009). Derbyshire, United Kingdom, Harlan Laboratories Limited (Unpublished report submitted by the Owner).
- Innospec (2009a) The Determination of the Specific Gravity of OLI9000.m (solvent stripped) (Project Reference AN200951944, December, 2009). Cheshire, United Kingdom, Innospec Ltd (Unpublished report submitted by the Owner).
- Innospec (2009b) Surface Tension Determination of [notified polymer] (solvent stripped) (Project Reference AN201050143, January, 2009). Cheshire, United Kingdom, Innospec Ltd (Unpublished report submitted by the Owner).
- Innospec (2010a) Melting Point Determination of OLI9000.m (solvent stripped) by DSC to OECD 102 (adopted 27/07/1995) (Project Reference AN201050024, January, 2010). Cheshire, United Kingdom, Innospec Ltd (Unpublished report submitted by the Owner).
- Innospec (2010b) Boiling Point Determination of OLI9000.m (solvent stripped) by DSC to OECD 103 (adopted 27/07/1995) (Project Reference AN201050025, January, 2010). (Unpublished report submitted by the Owner).
- Innospec (2010c) Water solubility (Report Number IRN 0001, April, 2010). Innospec Ltd., Cheshire, United Kingdom (Unpublished report submitted by the Owner).
- Innospec (2010d) The Determination of the Flash Point of OLI9000.m (solvent stripped) by Pensky-Martins Closed Cup (Project Reference AN201050047, January, 2010). Cheshire, United Kingdom, Innospec Ltd (Unpublished report submitted by the Owner).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-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>.