

File No: LTD/1459

April 2010

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

FULL PUBLIC REPORT

Z-106

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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
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Full Public Report**Z-106****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lubrizol International Inc. (ABN 52 073 495 603)

28 River Street

SILVERWATER NSW 2128

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical name, Other names, Molecular formula, Structural formula, Spectral data, Purity, Polymer constituents, Number average molecular weight, Residual monomer/other reactants, % Low molecular weight species, Import volume, Use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Water solubility, Hydrolysis as a function of pH, Dissociation constant, Flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-106 (product containing the notified polymer at <40% concentration in mineral oil)

CAS NUMBER

Not assigned

3. COMPOSITION

DEGREE OF PURITY

>90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Under normal use conditions, there would be natural loss of monomers or reactants from the notified polymer.

DEGRADATION PRODUCTS

The notified polymer is relatively stable. It is not expected to depolymerise under normal conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Amber coloured viscous liquid (75% notified polymer in diluent oil)

Property	Value	Data Source/Justification
Pour Point	21°C	Measured
Boiling Point	Not determined	Decomposed from 264°C
Relative Density	929 kg/m ³ at 20°C	Measured
Vapour Pressure	3 x10 ⁻⁶ kPa at 25°C	Measured
Water Solubility	≤0.0362 g/L at 20°C, pH 2 ≤0.0378 g/L at 20°C, pH 7	Measured as solution/extraction behaviour
Hydrolysis as a Function of pH	t _{1/2} >1 year, pH 8	Calculated for representative monomers using HYDROWIN (v2.00) (US EPA, 2009). The notified polymer contains hydrolysable functional groups, however hydrolysis is expected to be slow in the environmental pH range (4–9)
Partition Coefficient (n-octanol/water)	log Pow >9.40 at 40°C, pH 10.7 log Pow >8.05 at 40°C, pH 7 (corrected)	Measured
Adsorption/Desorption Dissociation Constant	log K _{oc} > 5.63 at 40°C, pH 6.4 pKa = 8.33 ± 0.28	Measured Calculated using estimation software ACD/I-lab Web Service (ACD/pKa 8.03). The notified polymer is expected to be ionised in the environmental pH range (4–9)
Particle Size	Not determined	Viscous liquid
Flash Point	155°C at 101.3 kPa	Measured
Flammability	Not expected to be highly flammable	Based on measured flash point
Autoignition Temperature	300°C	Measured
Explosive Properties	Not predicted to be explosive	Estimated based on chemical structure of the notified polymer

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is not an oxidiser and is considered to be stable and not reactive.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table, the notified polymer is not classified as hazardous according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the notified polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported at <40% in a solution with additional additives and diluent oil.

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

Year	1	2	3	4	5
Tonnes	<30	<300	<3000	<3000	<3000

PORT OF ENTRY

All major Australian ports

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will not be manufactured in Australia but will be imported and then transported to

various sites around Australia, where it will be used in formulating finished engine oil additive packages.

TRANSPORTATION AND PACKAGING

Solutions containing the notified polymer will be imported in drums (208 L) or isotainers and transferred to trucks for direct transport by road to customer's blending facilities.

USE

The notified polymer will be used as an engine oil viscosity modifier and will be present in the finished products at <5% concentration.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia and will be imported as a <40% solution with additional additives and diluent oil. The additive product containing the notified polymer will be further processed at customer's blending facilities.

A typical formulation operation would involve blending the engine oil additive product containing the notified polymer with diluent oil and additional additives to produce a finished engine oil product. The additive product containing the notified polymer will be pumped from isotainers (20 tonnes) or decanted from drums (208 L) to vessels where it will be mixed with oil and possibly other additives. After blending, the finished engine oil products, which contain the notified polymer at <5%, would be packaged into drums, isotainers or smaller containers for transport/sale. Packaging equipment is expected to be automated and housed within or near the blending operation area. The blending facility is expected to be well ventilated and fully automated.

The finished engine oil containing the notified polymer will be supplied in bulk to automobile manufacturers for 'factory fill' applications. Additionally, it may also be supplied in smaller containers for use in service applications through garages or sold to the public for DIY use.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

The number and category of workers involved in the use of the notified polymer is not available. However, it is expected that several workers would be involved in handling the notified polymer as imported in the additive package at reformulation sites. In addition, a number of workers at automobile manufacturing facilities and mechanical workshops are expected to handle the finished engine oil products containing the notified polymer. Therefore, a considerable number of workers are expected to be involved in the transportation, reformulation and use of products containing the notified polymer.

EXPOSURE DETAILS

Transport and storage workers will not be exposed to the notified polymer, except in the case of an accidental spillage involving damage to the packaging.

The blending facility is expected to be well ventilated and fully automated with limited potential for exposure. Exposure to the notified polymer at <40% during blending is expected to be limited to: transfer of the notified polymer into mixing vessels, connection and disconnection of hoses, residues in hoses, and occasionally from leaks and spills. Dermal contact is expected to be the main route of occupational exposure. Some inhalation exposure could occur if mists are generated during blending processes. Workers are expected to wear personal protective equipment (PPE) including protective aprons, nitrile or neoprene gloves and boots as appropriate during reformulation to minimise exposure to the notified polymer. Ventilation is expected to be in place to minimise inhalation exposure to the notified polymer.

At vehicle manufacturers, the finished engine oil will be added to engines using automated systems and exposure is unlikely. However, dermal exposure from drips, spills and splashes as well as from handling equipment contaminated with engine oil is possible. Workers are expected to wear PPE such as long sleeve shirts and gloves to minimise dermal exposure. Ocular exposure would be minimised if goggles are worn during transfer of engine oils containing the notified polymer (<5%).

Workers, such as mechanics, may be exposed to engine oils containing the notified polymer at less than 1% during use in mechanical workshops. Workers may experience dermal exposure and to a lesser extent, ocular exposure from drips, spills and splashes during draining and filling engines with oil products. The potential for dermal and ocular exposure may be reduced by wearing gloves, long sleeve shirts and goggles. Overall, exposure to the notified polymer is expected to be low, given the low concentration (<5%) of the notified polymer in the finished engine oils.

6.1.2. Public exposure

The notified polymer will be used as an engine oil viscosity modifier at <5% and once added to the engine, the general public will not be exposed to the notified polymer. Draining or filling of engines with the engine oil is expected to be undertaken by certified mechanics in most cases. However, do-it-yourself (DIY) users may experience inadvertent dermal and ocular exposure to finished engine oils containing <5% of the notified polymer when adding and/or replacing engine oil in their vehicles.

Overall, public exposure is expected to be limited due to its infrequent use and the low concentration of the notified polymer in finished engine oil.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer (75% in diluent oil) are summarised in the table below.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

The notified polymer is not expected to be absorbed orally, dermally or via inhalation given its high molecular weight (> 10,000 Da.), low water solubility (<0.04 g/L) and high partition coefficient (log Pow > 8).

Acute toxicity

The notified polymer (75% in diluent oil) was found to be of low acute oral toxicity in a study in rats conducted according to OECD TG 420 (Harlan Laboratories, 2009c). No mortalities or adverse effects were observed during the study. The acute oral LD50 was determined to be > 2000 mg/kg bw.

Irritation and Sensitisation.

No information was provided on the irritation or sensitisation potential of the notified polymer. However, the notified polymer has a reactive functional group with a functional group equivalent weight (FGEW) of <5000. A monomer containing the reactive functional group was found to be corrosive to the eye and severely irritating to the skin in rabbits (OECD SIDS, 2002).

The monomer containing the reactive functional group was found not to be a skin sensitiser.

Mutagenicity

The notified polymer (75% in diluent oil) was found not to be mutagenic when tested at up to 5000 µg/plate in a bacterial reverse mutation test conducted in the presence and absence of metabolic activation in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2uvrA⁻ according to OECD TG 471 (Harlan Laboratories, 2009d).

Health hazard classification

Based on the limited data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified polymer is a high molecular weight polymer with low acute oral toxicity and no known potential for genotoxicity. The notified polymer contains a functional group with FGEW < 5000 which may cause corrosion to the eyes and irritation to the skin. The corrosion/irritation risk would be greatest for workers handling the notified polymer at <40% concentration in the imported formulation.

Exposure of workers handling formulations containing the notified polymer at up to <40% at reformulation sites is expected to be minimised by the use of automated and enclosed systems as well as PPE. These measures should ensure that dermal and ocular exposure is minimised and therefore the risk of eye corrosion or skin irritation is not considered unacceptable.

Workers in vehicle manufacturing facilities are not expected to experience eye or skin irritation due to the use of PPE and also due to the lower concentration of the notified polymer (<5%) in finished engine oils.

Workers in mechanical workshops handling finished engine oils are not expected to experience eye or skin irritation due to the low concentration of the notified polymer (<5%) in engine oils. Although the use of PPE would further minimise any risk of irritation.

6.3.2. Public health

Members of the public may encounter infrequent dermal and ocular exposure to the notified polymer at <5% during draining and filling of engine oils. However, due to the low concentration of the notified polymer in the engine oil and the infrequent use, the risk to public health is not expected to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be used as an engine oil viscosity modifier and blended into the finished product in Australia. At the blending facilities release during the highly automated blending process is not expected. The equipment used will typically be cleaned with oil, with these washings used in the formulation of the next batch or another oil blend. Accidental spills, and residue of the notified polymer remaining in import containers (<5% of the contents), are expected to be contained and disposed to landfill or recycled.

RELEASE OF CHEMICAL FROM USE

Minor spills may occur during addition and removal of oil to machines. For vehicle applications the majority (~86%) of oil changes take place in specialised automotive service centres, where release of the product containing the notified polymer from professional activities is expected to be disposed of appropriately in landfill, by thermal decomposition or recycling (AIP, 1995). The majority of recycled oil will be reused as burner oil (e.g. in kilns, furnaces and industrial burners). The DIY proportion (~14%) of oil changes could potentially lead to improper disposal of approximately half the used oil to soils, sediments and storm water drains. Approximately 25% of engine oil (and thus notified polymer) is consumed during operation, and <0.5% of engine oil is estimated to be lost from leaks past seals and gaskets.

RELEASE OF CHEMICAL FROM DISPOSAL

Isotainers 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.

Used oil drained from crankcases at specialised automotive service centres (approximately 75%) is expected to be disposed of to oil recycling centres.

Only around 20% of used oil removed by DIY enthusiasts is collected for recycling. Approximately 25% is buried or disposed of to landfill, 5% is disposed of into storm water drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways (Snow, 1997). In a worst case scenario, whereby DIY enthusiasts dispose of oil to sewer, up to 0.7% (i.e. 5% x 14%) of the total import volume could potentially be released to the aquatic environment.

7.1.2 Environmental fate

No environmental fate data were submitted. Most of the notified polymer will be thermally decomposed during engine operation or through re-use as an energy source. Smaller amounts may be consigned to landfill, or disposed of inappropriately to land or stormwater. Disposal to land or landfill would result in its immobilisation because of the strong sorption to soil organic carbon. If disposed of to water, the notified polymer is likely to adsorb to suspended solids and sediment. Either in landfill or through thermal decomposition, the notified polymer will decompose into water and oxides of carbon and nitrogen. The notified polymer's high molecular weight will preclude absorption across biological membranes and thus it is unlikely to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

A worst case predicted environmental concentration (PEC) might be calculated if it is assumed that 0.7% of the notified polymer (maximum 21 tonnes) is released into stormwater drains in a single metropolitan area with a geographical footprint of 500 km² and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 21 tonnes and the annual volume of water drained from this region estimated to be approximately 250 x 10⁶ m³, the resultant PEC is 84 µg/L. It should be stressed that this result reflects a worst case scenario, as in reality releases of the notified polymer would be more diffuse and at lower levels.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified polymer (75% in diluent oil) are summarised in the table below. Details of this study can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Algal Toxicity	E _r L50 (72 h) >100 mg/L	Not harmful to algae up to the limit of solubility

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the notified polymer is not harmful to algae up to the limit of its solubility in water. The endpoint of the study is based on a nominal loading rate due to the low water solubility of the notified polymer. The actual concentration of the notified polymer in the study was less than the limit of quantification (LOQ = 0.33 mg/L) (determined by HPLC), and therefore this value should be treated with caution.

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated using the algal acute toxicity endpoint (E_rL50 >100 mg/L) and an assessment factor of 1000, as the endpoint for only one trophic level is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E _r L50 (alga)	>100	mg/L
Assessment Factor	1000	
PNEC:	> 100	µg/L

7.3. Environmental risk assessment

Comparison of the PEC of 84 µg/L with the PNEC of >100 µg/L suggests the possibility of toxic effects in aquatic life exposed to residues of the notified polymer that have been inappropriately disposed of to stormwater. However, in practical terms the notified polymer is not expected to pose a risk to the environment. This is because the PNEC represents a conservative minimum and the PEC overestimates the likely level of exposure. The PEC reflects a worst case scenario with no consideration of the strong hydrophobicity of the notified polymer, which would favour sorption to sediment rather than dissolution in the water column. Therefore, the notified polymer is not expected to pose a risk to the environment when it is used as proposed in engine oils.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Based on the limited data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in the imported product Z-106 at <40% during reformulation:
 - Avoid contact with skin and eyes
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during handling of the imported product at formulation facilities:
 - Chemical resistant gloves
 - Coveralls
 - Safety glasses

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical 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 removal.

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 chemical 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 concentration of the notified polymer in imported products is $\geq 40\%$;
 - the concentration of the notified polymer in engine oil products is $\geq 5\%$;
- or
- (2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from a component of engine oils, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 3000 tonnes, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified 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 MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All physical and chemical properties were conducted on a product containing 75% notified polymer.

Pour Point	21°C
Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature. BS 2000 Part 15 (equivalent to ISO 3016).
Remarks	Pour point was measured due to the viscous heterogenous nature of the notified polymer.
Test Facility	Harlan Laboratories Ltd. (2009a)
Boiling Point	Not Determined
Method	EC Directive 92/69/EEC A.2 Boiling Temperature. ASTM E537-86.
Remarks	DSC method. As the test material decomposed from 264°C at 100.74 kPa prior to boiling, no value for boiling point could be determined.
Test Facility	Harlan Laboratories Ltd. (2009a)
Relative Density	929 kg/m ³ at 20 ± 0.5°C
Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	Harlan Laboratories Ltd. (2009a)
Vapour Pressure	3 x10 ⁻⁶ kPa at 25°C
Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Determined with a vapour pressure balance.
Test Facility	Harlan Laboratories Ltd. (2009b)
Water Solubility	≤0.0362 g/L at 20°C, pH 2 ≤0.0378 g/L at 20°C, pH 7
Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks	The solution/extraction behaviour of the test substance (75% notified polymer in diluent oil) was conducted in accordance with the guidelines above, at nominal concentrations of 1 g/L and 10 g/L, each at pH 2 and pH 7. The guidelines require particles in the size range 125–250 µm, however as the test substance is a viscous liquid it was used as received. After the test mixtures were shaken for approximately 24 h, the mixtures were visually observed to be clear with excess test material on the bottom and sides of the flask and centrifuging was not considered necessary. Sample concentrations were determined by total organic carbon (TOC) analyses, however, as the TOC results were reported to be variable and inconclusive the maximum gravimetric total extractables are quoted for each pH tested.
Test Facility	Harlan Laboratories Ltd. (2009a)
Partition Coefficient (n-octanol/water)	log Pow >9.40 at 40°C, pH 10.7 log Pow >8.05 at 40°C, pH 7 (corrected)
Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. The partition coefficient was determined by comparing the retention time of the test substance (75% notified polymer in diluent oil) to those of known standards. The mobile phase (methanol: water 85:15) was adjusted to pH 10.7 using ammonium hydroxide to obtain the test material in its unionised form. The dead time was determined to be 1.23 min (thiourea). The notified polymer eluted at 60.5 min, after the last calibration standard (38.3 min for 1-phenyl tridecane, log Pow = 9.40). Thus, the log Pow for the notified polymer is therefore determined to be >9.40 at pH 10.7. The partition coefficient log Pow corrected for pH 7, is >8.05. It is expected that the notified polymer will partition

from water to oil.
Test Facility Harlan Laboratories Ltd. (2009a)

Adsorption/Desorption $\log K_{oc} > 5.63$ at 40°C, pH 6.4

Method EC Directive 440/2008/EC C.19 Adsorption Coefficient
Remarks HPLC Method. The adsorption coefficient was determined by comparing the retention time of the test substance (75% notified polymer in diluent oil) to those of known standards. The mobile phase (methanol: water 55:45) was adjusted to pH 6.4 to obtain the test material in its ionised form. The dead time was determined to be 3.215 min (formamide). The notified polymer eluted at 37.3 min, after the last calibration standard (19.2 min for DDT, $\log K_{oc} = 5.63$). Thus, the $\log K_{oc}$ for the notified polymer is therefore determined to be >5.63 at pH 6.4 and it is expected that the notified polymer will partition from water to organic matter in soil and to sewage sludge.
Test Facility Harlan Laboratories Ltd. (2009a)

Flash Point $155 \pm 2^\circ\text{C}$ at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Remarks Determined using a closed cup equilibrium method.
Test Facility Harlan Laboratories Ltd. (2009b)

Autoignition Temperature $300 \pm 5^\circ\text{C}$

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks Determined by heating aliquots of the test material in a flask and observing for any ignition.
Test Facility Harlan Laboratories Ltd. (2009b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (75% in diluent oil)			
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.			
Species	<i>Desmodesmus subspicatus</i>			
Exposure Period	72 hours			
Concentration Range	Nominal: 100 mg/L (WAF) Actual: <LOQ			
Auxiliary Solvent	None			
Water Hardness	0.15 mmol Ca ²⁺ & Mg ²⁺ /L			
Analytical Monitoring	HPLC was used for determination of the concentration of the notified polymer			
Remarks - Method	After a range-finding test, algae with a density of 4 × 10 ³ cells per mL were exposed to a Water Accommodated Fraction (WAF), due to the low water solubility of the test material, at a single nominal loading rate of 100 mg/L (6 replicates). The test substance (250 mg) was added to the culture medium (2.5 L) to achieve the loading rate of 100 mg/L. The test medium was stirred for 23 h and allowed to stand for 1 h. The WAF was removed by mid-depth siphoning (discarding the first 75–100 mL). Microscopic inspection of the WAF showed no micro-dispersions or undissolved test material to be present. The test mixtures were irradiated 24 h/day at pH 7.2–7.9 and 24 ± 1°C for a period of 72 hours. The positive control was provided by potassium dichromate (0.0625–1.0 mg/L). A student's t-test incorporating Bartlett's test for homogeneity of variance was carried out on the data to determine any statistically significant differences between test and control groups.			
RESULTS				
	<i>Biomass</i>		<i>Growth</i>	
	<i>E_bL₅₀</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>	<i>E_rL₅₀</i> <i>mg/L at 72 h</i>	<i>NOEL</i> <i>mg/L</i>
	>100	100	>100	100
Remarks - Results	Under the same conditions as for the test substance the E _b C ₅₀ and E _r C ₅₀ values for the positive control were 0.30 mg/L (95% CI: 0.27–0.34 mg/L) and 0.79 mg/L (95% CI reported to be not possible to calculate) respectively, which were within the normal range for this reference material. Cell growth of the control increased 47-fold after 72 h, thus validating the test.			
	The actual concentrations of the notified polymer in the test medium were determined by HPLC to be less than the limit of quantification (LOQ = 0.33 mg/L). Therefore, these values should be treated with caution.			
CONCLUSION	The notified polymer is not harmful to algae up to the limit of its solubility in water			
TEST FACILITY	Harlan Laboratories Ltd. (2009e)			

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- Harlan Laboratories Ltd (2009c) Notified polymer: Acute Oral Toxicity in the Rat – Fixed Dose Method. Project Number: 0525/0961. Harlan Laboratories Ltd. Derbyshire, UK. 13 August 2009 (Unpublished report provided by notifier).
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