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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-101

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
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Z-101

1. APPLICANT AND NOTIFICATION DETAILS

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

Valvoline (Australia) Pty Ltd (ABN 86 000 446 855)
30 Davis Road
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 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-101 (solution containing the notified polymer at 80% concentration in mineral oil)

MOLECULAR WEIGHT
Mn Value >10,000 Da.

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

3. COMPOSITION

DEGREE OF PURITY >95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Residual monomers of the notified polymer are known to be irritating to eyes and skin (R36/38) and may cause sensitisation by skin contact (R43). However, each of the individual monomers will be present at a concentration below the cut-off for classification as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellow viscous liquid (80% notified polymer in mineral oil)

Property	**Value**	**Data Source/Justification**
Pour Point	44°C	Measured
Boiling Point	Decomposes at >313°C	Forms a black viscous liquid when decomposed
Density	927 kg/m^3 at 27°C	Measured
Vapour Pressure	1.6 x 10^{-7} kPa at 25°C	Measured
Water Solubility	2.95 × 10^{-3} g/L at 1 g/L load at 20°C 19.8 × 10^{-3} g/L at 10 g/L load at 20°C	Measured as solution/extraction behaviour
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functional groups, however, hydrolysis is expected to be very slow in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	log Pow >9.40 at 40°C	Measured
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil, sediment and sewage sludge based on its high molecular weight and high partition coefficient.
Dissociation Constant	Not determined	The notified polymer contains functional groups that are expected to be ionised in the environmental pH range (4–9).
Flash Point	162°C at 101.3 kPa	Measured
Flammability	Not expected to be highly flammable	Based on measured flash point
Autoignition Temperature	352°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 stable in air and in the presence of moisture.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified as dangerous according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does 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 polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia, but will be imported either in a formulation containing 50% of the notified polymer in mineral oil or as a component of finished engine oil products at < 1%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes					
Lubrizol	<1	<1	<5	<5	<5
Valvoline	<1	<1	<1	<1	<1

PORT OF ENTRY
All major Australian ports

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified polymer will not be manufactured in Australia but will be imported as an additive package and then shipped to various sites around Australia where it will be used in formulating engine oil additive packages. Alternatively, the notified polymer will be imported in finished engine oil products ready for use in vehicles.

TRANSPORTATION AND PACKAGING
A 50% solution of the notified polymer in mineral oil will be imported in 208 L drums or 1041 L isotainers and transported by road directly to the notifiers blending facilities.

Finished engine oil products containing the notified polymer at <1% will be imported in various containers ranging from 0.9 L bottles to 204 L drums and transported by road for sale.

USE
The notified polymer will be used as an engine oil viscosity modifier and will be present in the finished products at <1% concentration.

OPERATION DESCRIPTION
The notified polymer solution will be imported into major Australian ports and then transported by road to customer sites where it will be pumped from the import containers into storage tanks. It will then be pumped from these holding tanks to mixing tanks where it will be blended with other additives into finished engine oil products. These products will then typically be pumped into drums and smaller aftermarket containers for transport. All these operations will be carried out either automatically or semi-automatically in closed systems conducted in well-ventilated environments.

Finished engine oil products reformulated in Australia or imported directly from overseas will be added to engines in new vehicles at vehicle manufacturing operations or added to vehicles by mechanics in mechanical workshops. A small portion may also be used by do-it-yourself (DIY) users who replace engine oils in their vehicles.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS
The precise number of workers involved in handling, blending and end use of the notified polymer is not known.

EXPOSURE DETAILS
Transport and storage
Transport and storage workers are not likely to be exposed to the notified polymer except in the case of an accident involving damage to the packaging.

Blending of engine oil products
Blending is expected to be fully automated and ventilated with limited potential for exposure. However, there is some potential for exposure to the notified polymer at <50% for workers during transfer of the imported solution to mixing vessels, spills, and during coupling and decoupling of hoses. The main route of exposure is expected to be dermal, although some ocular exposure is also possible. Inhalation exposure is not anticipated to be significant given the low vapour pressure of the notified polymer and the use of ventilation. Catching pans

are expected to be used to capture and therefore minimise the potential for exposure to spills. In addition, workers are expected to wear nitrile or neoprene gloves, safety goggles, a long sleeve shirt or apron and boots to minimise exposure.

The packaging equipment is expected to be automated and housed within or near the blending operation area. Dermal and ocular exposure may occur during packaging, however workers are expected to wear aprons, gloves and safety goggles to minimise exposure.

End use
Workers may be exposed to engine oils containing the notified polymer at less than 1% during use in vehicle manufacturing or mechanical workshops.

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 (< 1%).

At mechanical workshops, professional users such as mechanics may experience dermal or ocular exposure to the final product containing the notified polymer at <1% when transferring engine oil to cars and other machinery. The potential for dermal and ocular exposure may be reduced by wearing gloves, long sleeve shirts and goggles. Overall, exposure to the notified polymer will be low, given the low concentration (< 1%) of the notified polymer in the finished engine oils.

6.1.2. Public exposure

The notified polymer will be used as a component of engine oils at < 1% concentration. The public are not expected to be exposed to engine oil containing the notified polymer unless they perform maintenance on their vehicles. DIY users adding or replacing engine oils containing the notified polymer at <1% may experience dermal and ocular exposure, however this is expected to be infrequent.

Overall, public exposure to the notified polymer is expected to be limited due to its infrequent use and low concentration (< 1%) in finished engine oil.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer (~80% in mineral oil) are summarised in the table below.

Endpoint	*Result and Assessment Conclusion*
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, high partition coefficient (log Pow > 9) and low vapour pressure (< 1.6×10^{-7} kPa).

Acute toxicity
The notified polymer (~80% 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 Da. 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). A monomer containing the reactive functional group was found not to be a skin sensitiser (OECD SIDS, 2002).

Although the notified polymer contains residual monomers that are known to be irritating to the eyes and skin and may cause skin sensitisation they will be present at levels below the classification cut-offs for these effects.

Mutagenicity
The notified polymer (~80% 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 acute oral toxicity data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). In the absence of data on other health endpoints, the notified polymer is not classifiable 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. There may be potential for eye and skin irritation and skin sensitisation.

Exposure of workers handling formulations containing the notified polymer at up to 50% at reformulation sites is expected to be minimised by the use of automated and enclosed systems as well as PPE.

Workers in vehicle manufacturing facilities and mechanical workshops handling finished engine oils are not expected to experience irritation due to the low concentration of the notified polymer (< 1%) and the use of PPE by workers in vehicle manufacturing facilities.

Overall, the notified polymer is not considered to present an unacceptable risk to the health of workers in formulation plants or when used in finished engine oils due to the anticipated low exposure from use of PPE (overalls/apron, safety glasses and gloves).

6.3.2. Public health
Members of the public may encounter infrequent dermal and ocular exposure to the notified polymer at <1% during draining and filling of engine oils. However, due to the low concentration of the notified polymer in the engine oil the risk to public health is not considered to be unacceptable.

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 for use 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 (<1% 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. Release of the product containing the notified polymer used in 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 “do-it-yourself” (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) will be 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% will be buried or disposed of to landfill, 5% will be disposed of into storm water drains and the remaining 50% will be 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% × 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, nitrogen and sulphur. 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 42 kg) is released into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 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 42 kg and the annual volume of water drained from this region estimated to be approximately 250 x 10^6 m^3, the resultant PEC is 0.17 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 (80% in diluent oil) are summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	E_rL50 (72 h) >100 mg/L	Not toxic 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 toxic 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 total organic carbon (TOC) concentration of the notified polymer in the study was less than the TOC of the control, and therefore these results were not used.

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_rL50 (alga)	>100	mg/L
Assessment Factor	1000	
PNEC:	> 100	μg/L

7.3. Environmental risk assessment

The risk quotients (Q = PEC/PNEC) are tabulated below:

Risk Assessment	PEC μg/L	PNEC μg/L	Q
Q - River	0.17	>100	**<0.0017**
Q - Ocean	0.01	>100	**<0.0002**

A Q value < 1 indicates that the notified polymer is not expected to pose any unacceptable risk to aquatic life, even under the conservative exposure assumptions outlined above. The PEC overestimates the likely level of exposure, as it reflects a worst case scenario with no consideration of the hydrophobicity of the notified polymer, which would favour sorption to sediment rather than dissolution in the water column. 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

Hazard classification

Based on the acute oral toxicity data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). In the absence of data on other health endpoints, the notified polymer is not classifiable according to 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 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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered 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 as imported at 80% concentration:
  - *Avoid contact with eyes and skin*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as imported at 80% concentration:
  - *Eye/face protection*
  - *Gloves*
  - *Overalls/apron*

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

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 engine oil products is ≥ 1%;

or

(2) Under Section 64(2) of the Act; if
  – the function or use of the polymer has changed from an engine oil viscosity modifier, 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 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

Pour Point 44°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	The viscous heterogenous nature of the notified polymer meant that determination of Pour point was considered most appropriate.
Test Facility	Harlan Laboratories Ltd (2009a)

Boiling Point >313°C (decomposes) at 100.8 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The notified polymer decomposed from 313°C forming a black viscous liquid.
Test Facility	Harlan Laboratories Ltd (2009a)

Density 927 kg/m^3 at 27°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Given the viscous nature of the notified polymer the pycnometer method was considered impractical and a gas comparison pycnometer was adopted instead.
Test Facility	Harlan Laboratories Ltd (2009a)

Vapour Pressure 1.6×10^{-7} kPa at 25°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Temperature and pressure readings were taken between 100 to 110°C with a one hour dwell time at 100°C between runs.
Test Facility	Harlan Laboratories Ltd (2009b)

Water Solubility 2.95×10^{-3} g/L at 1 g/L load at 20°C
19.8×10^{-3} g/L at 10 g/L load at 20°C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water
Remarks	The test substance (80% notified polymer in diluent oil) was observed to have a very low solubility in water and, as it was a complex mixture of reaction products, it was considered more appropriate to determine extractables using loading rates of 1 and 10 g/L. The concentration of extractables was determined by measuring total organic carbon (TOC). Predicted water solubility values for a representative structural unit were 0.13 mg/L (WSKOW (v1.41)) and 0.12 mg/L (WaterNT (v1.01)) (US EPA, 2009). These values were reduced by the further addition of monomer units and alkyl chains. The higher than expected results from the TOC analysis were reported to probably be due to impurities and starting products.
Test Facility	Harlan Laboratories Ltd (2009a)

Partition Coefficient (n-octanol/water) log Pow >9.40 at 40°C

Method	OECD TG 117 Partition Coefficient (n-octanol/water)
Remarks	HPLC Method. The partition coefficient was determined by comparing the retention time of the test substance (80% notified polymer in diluent oil) to a calibration curve prepared from known standards (log Pow range 1.1–9.4). The dead time was determined to be 1.56 min (thiourea). The notified polymer eluted at ~84 min, after the last calibration standard (1–phenyl tridecane, log Pow = 9.4, retention time = 50.3 min), and the partition coefficient was determined to be $>2.51 \times 10^{9}$ and log Pow > 9.40. The notified polymer is expected to partition from water to oil.

Test Facility	Harlan Laboratories Ltd (2009a)

Flash Point 162°C at 101.3 kPa

Method	EC Directive 92/69/EEC A.9 Flash Point.
Test Facility	Harlan Laboratories Ltd (2009b)

Autoignition Temperature 352 ± 5°C

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases). EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Test Facility	Harlan Laboratories Ltd (2009b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (80% in diluent oil)
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L (WAF) Actual: 0 mg/L
Auxiliary Solvent	None
Water Hardness	0.15 mmol Ca^{2+} & Mg^{2+}/L
Analytical Monitoring	Total organic carbon (TOC) analysis using a shimadzu TOC-V to determine the concentration of the notified polymer in sample solution.
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 surface of 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 7.0–7.9 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

Biomass		*Growth*	
E_bL_{50} mg/L at 72 h	*NOEL mg/L*	*E_rL_{50} mg/L at 72 h*	*NOEL mg/L*
>100	100	>100	100

Remarks - Results	Under the same conditions as for the test substance the E_bC_{50} and E_rC_{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 128-fold after 72 h, thus validating the test. The actual TOC concentrations of the notified polymer in the test media were determined to be less than the TOC of the control. Therefore, these values should be treated with caution. The results were based on the nominal loading rates only.
CONCLUSION	The notified polymer is not toxic to algae up to the limit of its solubility in water
TEST FACILITY	Harlan Laboratories Ltd. (2009e)

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