

File No: EX/185 (LTD/1430)

September 2013

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

PUBLIC REPORT

Z-100

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 Sustainability, Environment, Water, Population and Communities.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

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Public Report

This assessment report is for an extension of original assessment certificate for Z-100. Based on the submission of new information by the extension notifiers, some sections of the original assessment report have been modified. These modifications have been made under the heading '*Extension Application*' in the respective sections.

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
EX/185	The Shell Company Co of Australia Ltd	Z-100	ND	≤ 100 kg per annum	Component of diesel engine oil

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data, the notified polymer is not 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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Risk assessment relating to extension application

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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 chemical 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 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 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(2) of the Act; if
 - the function or use of the chemical has changed from diesel engine oil additive, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of 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.

Extension Application:

The applicant for the extension application has provided an MSDS of a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Holder of Original Assessment Certificate (LTD/1430)

Lubrizol International, Inc. (ABN 52 073 495 603)
28 River Street
Silverwater NSW 2118

Applicant for an Extension of the Original Assessment Certificate:

The Shell Company of Australia Ltd (ABN 46 004 610 459)
PO Box 872K, GPO,
Melbourne VIC 3001

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, structural formula, number average molecular weight, molecular weight, means of identification, purity, non-hazardous impurities, use details, import volume, weight percentage and ingredient, residual monomers, low molecular weight polymer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Particle size.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Nil

NOTIFICATION IN OTHER COUNTRIES

Nil

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-100 (product containing <10% notified polymer)

CAS NUMBER

Not assigned

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

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

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

ADDITIVES/ADJUVANTS None

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: Black solid block (notified polymer), Amber viscous liquid (solution in diluent oil, -Z-100)

Property	Value	Data Source/Justification
Melting Point/Freezing Point (Pour Point)	79°C	Measured
Boiling Point	401°C	Measured
Relative Density	0.940 at 20°C	Measured
Vapour Pressure	$< 4.1 \times 10^{-7}$ kPa at 25°C	Measured
Surface Tension	-	Not determined as water solubility was determined to be < 1 mg/L.
Water Solubility	$< 5.0 \times 10^{-5}$ g/L at 20°C	Measured. Below the limit of quantification (LOQ).

Hydrolysis as a Function of pH	Not determined	The notified polymer is expected to be hydrolytically stable based on its low solubility in water and the absence of readily hydrolysable functions
Partition Coefficient (n-octanol/water)	$\log P_{OW} > 9.4$	Measured
Adsorption/Desorption	$\log K_{oc} > 5.63$	Measured
Dissociation Constant	Not determined	The notified polymer has weakly basic functions but will not be ionized in the environmental pH range of 4-9.
Particle Size	Not determined	As the notified polymer will be sold as viscous liquid (Z-100), the particle size test is not applicable.
Flash Point	$>200^{\circ}\text{C}$	Flash point was measured on Z-100, using in-house testing and ASTM D 93 method.
Flammability (Solids)	Not highly flammable.	Measured (based on preliminary screening test only)
Autoignition Temperature	$>400^{\circ}\text{C}$	Measured
Oxidising properties	Not predicted to be an oxidising agent.	Estimated based on chemical structure.
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.

5. INTRODUCTION AND USE INFORMATION

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

Original Application:

The notified polymer will be imported into Australia in an additive package, with a final concentration of the notified polymer in Z-100 at $<10\%$.

Extension Application:

The notified polymer will be imported into Australia as a component in packaged diesel engine oil, Helix HX5 15W40, in 1L, 5L, 20L and 209L packages. Z-100 will be present in the diesel engine oil at concentrations less than 1.2 %.

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

Original Application:

Year	1	2	3	4	5
Tonnes	30-100	300-1000	300-1000	1000-3000	1000-3000

Extension Application:

Year	1	2	3	4	5
Kilograms	20-40	30-60	40-80	50-90	50-100

PORT OF ENTRY

Original Application:

Not known.

Extension Application:

Brisbane and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will not be manufactured in Australia and will be imported into Australia in an additive package for diesel engine oil. Further blending and packaging of diesel engine oil containing the notified polymer will occur at different sites in Australia.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia in an additive package in isotainers or drums. These containers would then be transported directly to customer's blending facility.

USE**Original Application:**

The notified polymer will be used as a dispersant in diesel engine oil at concentrations of < 10%.

Extension Application:

The notified polymer will be used as a dispersant in diesel engine oil at concentrations of < 1.2%

OPERATION DESCRIPTION**Original Application:**

The notified polymer will be imported into Australia in a diesel engine oil additive product at concentrations of <10%. The additive product containing the notified polymer will be further processed at customer's blending facilities.

A typical formulation operation would involve blending the diesel engine oil additive product containing the notified polymer with diluent oil and additional additives. After blending, the finished diesel engine oil product which contains the notified polymer at <10%, would be packaged into containers for transport/sale. All these operations are carried out automatically or semi-automatically in a closed system. Furthermore, the facility is expected to be well ventilated.

Extension Application:

The notified polymer will be imported into Australia as a component of the finished diesel engine oil product at a concentration of < 1.2%. No further reformulation will take place upon arrival.

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 the products containing the notified polymer would be used by workers in mechanical workshops and vehicle manufacturing factories. Therefore, a considerable number of workers are expected to be involved in the transportation, distribution and the use of products containing the notified polymer.

EXPOSURE DETAILS**Original Application:**

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.

The blending facility is expected to be well ventilated and fully automated. Therefore, exposure during blending will be negligible and will mostly be limited to transfer operations in mixing vessels, during coupling, residues in lines, and occasionally from leaks and spills. Dermal contact would be the main route of occupational exposure. Some inhalation exposure could occur if mists are generated during blending processes. Workers are expected to take usual safety measures to wear protective aprons and use nitrile or neoprene gloves and boots as appropriate during various procedures to minimise exposure to the notified polymer.

Workers may be exposed to engine oils containing the notified polymer at less than 10% during use in vehicle manufacturing or mechanical workshops.

At car manufacturers, the finished diesel engine oil is expected to be added to engines using a mechanical transfer and exposure is unlikely. There is a potential for dermal exposure from drips, spills and splashes as well as from handling equipment contaminated with diesel engine oil. Workers are expected to wear appropriate personal protective equipment (PPE) to minimize dermal exposure. Overall, exposure to the notified polymer will be low, given the low concentration (<10%) of the notified polymer in the finished diesel engine oils.

At mechanical workshops, professional users such as mechanics may experience dermal or ocular exposure to the final product containing the notified polymer at 10%, when adding the diesel engine oil to the automobile and other machinery. The risk of both dermal and ocular exposure may be reduced by wearing appropriate PPE.

Extension Application:

Under the extension, exposure to workers is expected to be less than that of the original assessment, as blending will not be carried out in Australia.

6.1.2. Public exposure

Original Application:

The notified polymer will be used as a dispersant in diesel engine oil. Therefore, once engine oil containing the notified polymer is added to the engine, the general public will not be exposed to the notified polymer in the engine oil. Furthermore, exposure during the addition of engine oil to the general public is also expected to be minimal as most diesel engine oils are added and/or replaced by certified mechanics. However, DIY users may experience inadvertent dermal and ocular exposure to final products containing <10% of the notified polymer when adding and/or replacing engine oil of their vehicles.

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

Extension Application:

Public exposure is expected to be similar under the original and extension applications.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. The details of the toxicological investigations conducted on the notified polymer can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro (Chinese Hamster Lung cell line)	non genotoxic

Toxicokinetics, metabolism and distribution.

No data were available to assess toxicokinetics, metabolism and distribution of the notified chemical. Based on high molecular weight (>1000 Da) and also high n-octanol value (log P_{ow} >9.4) of the notified polymer, the potentials of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure are limited.

Acute toxicity.

The notified polymer was of low acute oral toxicity in rats. Acute dermal and inhalation toxicity data were not provided.

Irritation and Sensitisation.

No data were available to assess eye or skin irritation and skin sensitisation potentials of the notified polymer.

Repeated Dose Toxicity.

No data were available to assess the repeat dose toxicity potential of the notified polymer.

Mutagenicity.

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation test and a genotoxicity assay in vitro. Therefore, the notified polymer is unlikely to be a genotoxic/mutagenic.

Health hazard classification

Based on the data provided, the notified polymer is not 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, based on submitted studies, was of low acute oral toxicity in rats and is not expected to be a genotoxic. Furthermore, based on high molecular weight and high n-octanol value, the potentials of the notified polymer to cross the GI tract by passive diffusion or to be dermally absorbed after exposure are limited. Therefore, the notified polymer is not expected to present significant health hazards to workers during its use.

Workers may be exposed to the notified polymer at less than 10% concentration during blending and change/addition of engine oil in vehicles manufacturing or mechanical workshops. However, the level of exposure is not expected to be significant considering the relatively low concentration of the notified polymer in these products and control measures including engineering controls, automated processes and the use of PPE. Therefore, overall risk of exposure to the notified polymer will be low and not considered to be unacceptable to the health of workers.

6.3.2. Public health

The notified polymer will be used as a dispersant in diesel engine oil. Therefore, once engine oil containing the notified polymer is added to the engine, the general public will not be exposed to the notified polymer. Furthermore, exposure during the addition of engine oil to vehicle is also expected to be minimal as diesel engine oils are mostly added and/or replaced by certified mechanics.

DIY users may experience inadvertent dermal and ocular exposure to final products containing <10% of the notified polymer when adding and/or replacing engine oil of their vehicles. Exposure would be minimised if users wear gloves, goggles and a long sleeved shirt. Overall, the risk of public exposure is expected to be limited due to its infrequent use and low concentration of the notified polymer in finished diesel engine oil. Therefore, the risk of exposure to general public is low and not considered to be unacceptable to the health of general public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be manufactured and blended overseas into additive packages, and will be imported into Australia in drums and isotainers for use as a dispersant in diesel engine oil. Further blending with other ingredients may be required at customer's blending facilities.

At the blending facilities (if it is applicable), 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. In these situations release would occur through accidental spills, which would be recycled or collected for proper disposal which will most likely be landfill. Any of the notified polymer remaining in the import containers, expected to be < 1% of the contents, would be washed out and recycled or collected for proper disposal which will most likely be landfill.

RELEASE OF CHEMICAL FROM USE

Some minor, diffuse exposure will result from spills during addition to and removal of oil from machines. For vehicle applications, around 86% of oil changes take place in specialised automotive service centres, where release of the notified polymer from professional activities should be disposed of appropriately. The remaining 14% will be removed by DIY enthusiasts. The DIY proportion of oil changes could potentially lead to improper disposal of used oil (55%) to soils or sediments and storm water drains.

RELEASE OF CHEMICAL FROM DISPOSAL

Iso-containers and drums should 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 may be sent to landfill.

Used oil drained from crankcases at specialised automotive service centres is expected to be disposed of to oil recycling centres.

A survey tracing the fate of used lubricating oil in Australia (Snow, 1997) found that only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in 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.

7.1.2 Environmental fate

The notified polymer is likely to be mainly disposed of by thermal decomposition as part of the process to recover the calorific value of used lubricants. Smaller amounts may be consigned to landfill, or disposed of inappropriately to land or stormwater. Thermal decomposition would destroy the notified polymer, while 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 spread across the surface of the water and sorb to suspended solids and sediment. Either in landfill or through thermal decomposition, the notified polymer will finally be decomposed into water and oxides of carbon and nitrogen. The notified polymer is not expected to be readily biodegradable, based on a study for ready biodegradation provided by the notifier. The notified polymer is water-insoluble and has high molecular weight, and therefore, is not expected to be bioavailable or bioaccumulative to aquatic organisms.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

A worst case 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 approximately 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 a single ecotoxicological study conducted on the notified polymer 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	EL50 > 100 mg/L (WAF)	Not harmful to algae up to the limit of the solubility in water

The notified polymer is not expected to be harmful to algae based on the test result.

7.2.1 Predicted No-Effect Concentration

The PNEC has been calculated by using the toxicity endpoint of > 100 mg/L for alga and an assessment factor of 1000 given only one test result is available.

EC50 (Alga)	>100	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	> 100	µg/L

7.3. Environmental risk assessment

The Risk Quotient ($RQ = PEC/PNEC$) can be calculated as < 0.84 by using the PEC of $84 \mu\text{g/L}$ for the worse case scenario and the calculated PNEC of $> 100 \mu\text{g/L}$. The calculated RQ value of < 1 indicates that the notified polymer is not expected to pose any unacceptable risk to the environment from its proposed use in diesel engine oil even under a hypothetical worst-case disposal scenario.

8. RISK ASSESSMENT*Extension Application:*

While the introduction volume will increase slightly, the proposed use of the notified polymer will not change significantly under the proposed extension. Therefore, the circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

All physical and chemical properties were conducted on a product containing >85% notified polymer.

Melting Point/Freezing Point (Pour Point) 79°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	As the test material was noted to be an extremely viscous and complex mixture, it was considered that pour point testing would be most applicable in this instance.
Test Facility	Harlan Laboratories Ltd. (2009a)

Boiling Point 401°C at 100.05 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	The DSC method was employed. Due to the complex nature of the test material, the onset of boiling was only approximated.
Test Facility	Harlan Laboratories Ltd. (2009a)

Relative Density 0.940 at 20 ± 0.5°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Testing was carried out using the buoyancy method, also known as the hydrostatic balance method, which is appropriate for both liquid and solid substances.
Test Facility	Harlan Laboratories Ltd. (2009a)

Vapour Pressure $< 4.1 \times 10^{-7}$ kPa at 25°C

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined with a vapour pressure balance. The temperature and pressure readings were taken between 65 and 75°C with a one hour dwell at 65°C. No statistical analyses were performed because the readings were too low and variable for a line of best fit to have any meaning. A maximum value of the vapour pressure at 25°C was estimated to be 4.062×10^{-7} kPa by imposing a regression slope on a chosen data point and by extrapolation to 25°C. The test material was a product containing > 85% of the notified polymer. This is not considered to have any significant effects on the endpoint for the notified polymer based on the high molecular weight and the high proportion of the notified polymer in the test material. The notified polymer is very slightly volatile.
Test Facility	Harlan Laboratories Ltd. (2009b)

Water Solubility $< 5.0 \times 10^{-5}$ g/L at 20°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. Mixtures of the test material with double-distilled water were shaken at approximately 30°C for a period of up to 72 hours followed by standing for no less than 24 hours at 20°C. The sample solutions were obtained by centrifugation and analysed by GPC. The water solubility was determined to be less than the limit of quantification of 5.0×10^{-5} g/L. The notified polymer is considered to be very slightly soluble in water. This is consistent with the predominantly hydrophobic structure of the polymer and the results of a water extractability test (OECD TG 120) which showed that < 0.005% per unit mass of polymer was extracted into water after 24 hours at 20°C.
Test Facility	Harlan Laboratories Ltd. (2009a)

Partition Coefficient (n-octanol/water)log P_{OW} > 9.4

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method: The notified polymer was not soluble in n-octanol ($< 5.6 \times 10^{-3}$ g/L) and the log P _{OW} could not be estimated by a preliminary flask test. For the HPLC measurement, the dead time was determined to be 1.733 minutes by using thiourea. The retention time for the components of the test substance was greater than for the most strongly adsorbed reference standard compound (1-phenyltridecane; log P _{OW} = 9.4).
Test Facility	Harlan Laboratories Ltd. (2009a)

Adsorption/Desorption
– screening testlog K_{oc} > 5.63

Method	OECD TG 121 Estimation of the Adsorption Coefficient (K _{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).
Remarks	HPLC screening method: The dead time was determined to be 2.84 minutes by using formamide. Testing was carried out at pH 6.3. The retention time of the test material was longer than DDT (log K _{OC} = 5.63). The notified polymer is expected to partition to soil, sediment and organic matter based on its low water solubility and mainly hydrophobic structure.
Test Facility	Harlan Laboratories Ltd. (2009a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

Toxicological investigations were conducted on a product containing >85% notified polymer.

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer								
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method (2001). EC Directive 2004/73/EC B.1 <i>bis</i> Acute Toxicity (Oral).								
Species/Strain	Rat/Wistar								
Vehicle	Arachis oil BP								
Remarks - Method	No significant protocol deviations. A preliminary test at dose levels of 300 mg/kg bw and 2000 mg/kg bw was conducted.								
RESULTS									
<table><tr><td><i>Group</i></td><td><i>Number and Sex of Animals</i></td><td><i>Dose mg/kg bw</i></td><td><i>Mortality</i></td></tr><tr><td>1</td><td>5 (F)</td><td>2000</td><td>0</td></tr></table>		<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>	1	5 (F)	2000	0
<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>						
1	5 (F)	2000	0						
LD50	>2000 mg/kg bw								
Signs of Toxicity	Hunched posture and pilo-erection were noted in one animal during the day of dosing. No other signs of systemic toxicity were noted for the duration of the study (14 days).								
Effects in Organs	No abnormalities were noted at necropsy.								
Remarks - Results	All animals showed expected gain in body weight over the observation period (14 days).								
CONCLUSION	The notified chemical is of low toxicity via the oral route.								
TEST FACILITY	Harlan Laboratories Ltd. (2009c)								

B.2. 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.			
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA			
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone			
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500, 5000 µg/plate b) Without metabolic activation: 50, 150, 500, 1500, 5000 µg/plate			
Vehicle	Tetrahydrofuran			
Remarks - Method	No significant protocol deviations. Concentrations were chosen on the basis of a range finding test. All controls and test groups were plated in triplicate.			
RESULTS				
<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	>5000	>5000	≥1500	Negative
Test 2	ND	>5000	≥1500	Negative

<i>Present</i>				
Test 1	>5000	>5000	≥1500	Negative
Test 2	>5000	>5000	≥1500	Negative

ND= No data available due to technical error

Remarks - Results	<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. A black precipitate was observed at and above 1500 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 bacterial strains, at any dose level either with or without metabolic activation.</p> <p>All the positive control chemicals used in the test induced marked increase 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 chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan Laboratories Ltd. (2009d)

B.3. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese Hamster Lung (CHL) cell line
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with phenobarbitone/β-naphthoflavone
Vehicle	Tetrahydrofuran
Remarks - Method	No significant protocol deviations.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	0*, 20, 40, 80, 160*, 320*, 480*, MMC 0.1*	6 hrs	18 hrs
Test 2	0*, 20, 40, 60, 80, 160*, 320*, 480*, MMC 0.5*	24 hrs	24 hrs
<i>Present</i>			
Test 1	0*, 20, 40, 80, 160*, 320*, 480*, CP 5*	6 hrs	18 hrs
Test 2	0*, 20, 40, 60, 80, 160*, 320*, 480*, CP 5*	6 hrs	18 hrs

*Dose levels selected for metaphase analysis.

MMC = mitomycin C

CP = cyclophosphamide

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation*</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	>1250	>480	≥40	Negative
Test 2	Not performed	>480	≥80	Negative
<i>Present</i>				
Test 1	>1250	>480	≥20	Negative

Test 2	Not performed	>480	≥40	Negative
*The precipitate became aggregated at the maximum dose level of 480 µg/mL in all exposure groups. Therefore, the selection of the maximum dose for metaphase analysis was based on the onset of the aggregated precipitating dose level and was 480 µg/mL.				
Remarks - Results	The vehicle (solvent) controls had frequencies of cells with aberrations within the range expected for the CH cell line. All positive controls induced highly significant increases in the frequency of cells with aberrations indicating the satisfactory performance of the test and of the activity of the metabolising system.			
CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster Lung (CHL) cell line treated in vitro under the conditions of the test.			
TEST FACILITY	Harlan Laboratories Ltd. (2009e)			

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

All the environmental and ecotoxicity tests were conducted on a product containing >85% notified polymer.

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer (> 85%)
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sewage sludge micro-organisms
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	DOC was measured using a Shimadzu TOC-5050A TOC analyser.
Remarks - Method	In the initial experiment conducted at a concentration of 10 mg C/L, the toxicity control (containing both the test material and the standard material sodium benzoate) attained less than 25% biodegradation after 14 days, indicating that the test material would be classified as exhibiting inhibitory effects according to the OECD Guidelines. Therefore, in the definitive test, the test material was exposed to activated sludge at a reduced level of 5 mg C/L in duplicates for 28 days at 21°C.
	The test material was dissolved in a tetrahydrofuran stock solution and adsorbed by coating onto silica gel prior to dispersion in culture medium (to aid the dispersion of the test material in the test medium and to increase the exposure area to the test organisms). The solvent was later removed by applying a stream of air and heat to the coated silica gel.
	The degradation of the test material was assessed by the determination of carbon dioxide produced. A control test with inoculum and silica gel, a reference test with sodium benzoate (10 mg C/L), and a toxicity control test (15 mg C/L) were conducted for validation purposes. All were conducted in duplicates except for the toxicity control where only a single flask was used.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
6	0	6	87
14	0	14	93
21	2	21	92
28	4	28	99

Remarks - Results	<p>All validation criteria given in the OECD Test Guideline were satisfied and the study is considered valid.</p> <p>The toxicity control test attained 64% degradation 14 DAT. Sodium benzoate attained 99% degradation after 28 days thereby confirming the suitability of the inoculum and test conditions. The degradation rates calculated from the DOC analysis were similar to those from inorganic carbon analysis.</p> <p>The test material attained 4% degradation after 28 days and therefore cannot be considered to be readily biodegradable under the conditions of OECD Guideline 301B.</p> <p>The test material was a product containing > 85% of the notified polymer. This is not considered to have any significant effects on the results for the</p>
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notified polymer given the very low degradation attained and the high proportion of the notified polymer in the test material.

CONCLUSION The notified polymer cannot be considered to be readily biodegradable.

TEST FACILITY Harlan Laboratories Ltd (2009f)

C.2. Ecotoxicological Investigations

C.2.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (> 85%)
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)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	TOC analysis of the WAF; HPLC analysis of the concentration of test samples; Coulter® Multisizer Particle Counter for cell density determination.
Remarks - Method	<p>Following a range finding test, <i>Desmodesmus subspicatus</i> with density of 4×10^3 cells/mL was exposed for 72 hours to a Water Accommodated Fraction (WAF) of the test material at $24 \pm 1^\circ\text{C}$ and pH 7.2-7.3. The test was conducted with six replicates.</p> <p>To prepare the WAF, 250 mg of the test material was suspended in 2.5 litres of culture medium to give a loading rate of 100 mg/L. The suspension was vigorously stirred for 23 hours followed by standing for 1 hour. The aqueous phase was removed by mid-depth siphoning (the first 75-100 mL discarded) to give the 100 mg/L loading rate WAF. Microscopic inspection of the WAF showed no micro-dispersion or undissolved test material to be present.</p>

RESULTS

<i>Biomass</i>		<i>Growth</i>	
<i>EL_b50</i> mg/L at 72 h (WAF)	<i>NOEL</i> 100 mg/L (WAF)	<i>EL_r50</i> mg/L at 72 h (WAF)	<i>NOEL</i> mg/L (WAF)
> 100	100	>100	100

Remarks - Results There were no statistically significant differences ($P \geq 0.05$) between the growth rates for the control (which were logarithmic) and the 100 mg/L loading rate WAF test group and, therefore, the NOEL based on growth was 100 mg/L loading rate WAF.

CONCLUSION The notified polymer is not harmful to algae up to the limit of its solubility in water.

TEST FACILITY Harlan Laboratories Ltd (2009g)

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