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

FULL PUBLIC REPORT

Z-50

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Lubrizol International Inc (ABN 52 073 495 603) 28 River St Silverwater NSW 2128.

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS No., molecular and structural formulae, number-average molecular weight, spectral data, purity, impurities, import volume and polymer details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, particle size, flammability limits and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

None.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

OS171579, OS41919 or OS89905 (when sampled to customers or sent to testing laboratories for evaluation)

1131-204742 (research number)

MARKETING NAME(S)

Z-50

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) > 1000

Weight Average Molecular Weight (Mw) > 1000

% of Low MW Species < 1000 > 25%

% of Low MW Species < 500 > 10%

SPECTRAL DATA Ultraviolet/visible (UV/Vis), infrared (IR) and nuclear magnetic resonance (NMR) spectra were provided.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD UV/Vis, IR and NMR spectroscopy

Remarks Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
One impurity at less than 20%, present in samples used for toxicity testing.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
One impurity at less than 25%.

ADDITIVES/ADJUVANTS
None.

DEGRADATION PRODUCTS
Not expected to depolymerise.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No loss under normal use.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The chemical will be imported as a component of a fuel additive package in isotainers.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 100	< 100	< 100	< 100	< 100

USE
Lubricity improver for diesel fuels.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
The notified chemical is imported in isotainers, transferred to the customer's storage tank and thence to a tank truck and service station tanks.

5.2. Operation Description

The isotainers containing the fuel additive package are transported by road to, at most, 2 refineries where it is transferred to a storage tank via fixed and flexible lines. The additive package is metered into diesel fuel as it is added to a tank truck at about 20 ppm. The fuel is delivered to service stations where it is transferred via a flexible hose to underground storage tanks. Consumers then pump the fuel into their vehicles.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Diesel blending operators	1 – 2 per site	Up to 8 hours per day	Up to 230 days per year

Exposure Details

Import, Transport and Storage

The notified polymer will be imported in isotainers and transferred to customer depots or terminals by road or rail. Occupational exposure of dockside or transport workers is not expected except in the event of an accidental spill.

Refinery/Terminal Facilities

The fuel additive package containing the notified polymer is transferred from the container to the customer's storage tank. It is then automatically metered into diesel fuel as it is pumped into a tank truck. Worker exposure may occur during transfer of the additive package from containers to storage tanks and during the transfer of the additive package from storage to fuel in tankers. Exposure is expected to be confined to dermal contamination to drips and spills during the connection and disconnection of transfer lines and equipment. Protective aprons, nitrile gloves, nitrile or neoprene boots and chemical goggles or face shields are recommended by the notifier for workers when handling the additive package and the worker environment is expected to be well ventilated.

End Use - Service Stations

At service stations, the fuel plus additive will be transferred via hoses and couplings from tanker trucks to underground tanks. Exposure of transport drivers, service station personnel and mechanics to 20 ppm notified polymer in the final fuel may occur due to spillage. Exposure is expected to be confined to dermal contamination with drips and spills during the connection and disconnection of transfer lines and dipping of tanks. Estimated numbers of workers and duration of exposure were not provided by the notifier.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No release of the notified polymer is expected at the customer site during transport and blending, except in the event of an accidental spill. Any spills occurring during blending operations are to be contained by inert material and collected for disposal by incineration. The notifier has indicated the customer will be using a fully automated and closed blending unit, which controls and monitors the blending process, and includes safety features, such as spill containment and explosion-proof controls. Approximately 1% of the additive may remain in the import containers after emptying. This equates to less than 1 tonne per year, assuming the maximum yearly import volume. The isotainers and any residual product will be sent to a reconditioning facility, where they are to be cleaned with mineral oil and the residues disposed of by incineration.

RELEASE OF CHEMICAL FROM USE

No release of the notified chemical is expected at end use because the notifier expects the substance will be consumed in the automotive engine along with the diesel to generate primarily carbon dioxide and water.

5.5. Disposal

Incineration is the recommended disposal method. Spills occurring on land can be scraped up and incinerated. Spills occurring on water are expected to float on the surface and can be skimmed off with absorbent material for incineration.

5.6. Public exposure

It is expected that during import, transport, storage, mixing with fuel, and replenishment at service stations, exposure of the general public to the notified polymer will be low, except in the event of an accidental spill. Public exposure to the notified polymer will occur during refuelling of vehicles at petrol stations. Exposure is likely to be by the inhalation and dermal routes, with the possibility of ocular and oral exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear, brown highly viscous liquid.

Melting Point 42°C (pour point)

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
TEST FACILITY Safepharm Laboratories Limited (2002).

Density 954 kg/m³ at 20°C

METHOD EC Directive 92/69/EEC A.3 Relative Density.
Remarks Pycnometer method.
TEST FACILITY Safepharm Laboratories Limited (2002).

Vapour Pressure Estimated at $< 6 \times 10^{-8}$ kPa at 25°C.

Remarks Estimated from the vapour pressure of a similar polymer notified as LTD/1040. It should be noted that the polymer notified as LTD/1040 was a salt of the notified polymer and would be expected to have a lower vapour pressure. The vapour pressure of the notified polymer is not expected to be significant given its moderate molecular weight.

Water Solubility $< 5.61 \times 10^{-4}$ g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: GPC
Samples of the test material were shaken with in water at 30°C and then allowed to stand for 24 h before centrifugation and analysis of the supernatant using gel permeation chromatography.
TEST FACILITY Safepharm Laboratories Limited (2002).

Hydrolysis as a Function of pH Not determined – no groups which may be expected to hydrolyse.

Partition Coefficient (n-octanol/water) log Pow > 8

METHOD Calculated using KOWWIN version 1.66
Remarks Determined for a similar polyisobutylene polymer using fragment–constant methodology using proprietary software.

Adsorption/Desorption log K_{oc} > 4.26

Remarks Determined for a similar polymer using Quantitative Structure Activity Relationships (QSARs) from the EU Technical Guidance Documents.

Dissociation Constant Not determined

Remarks The notified polymer contains carboxylic acid moieties which would be expected to display characteristic acidity.

Particle Size Not applicable.

Flash Point 175°C

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Flammability Limits	Not determined.
Remarks	The notified polymer has a low vapour pressure.

Autoignition Temperature	> 400°C
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METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
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Explosive Properties	Not determined.
Remarks	Not expected to be explosive.

Reactivity	
Remarks	Not an oxidiser and not expected to be strongly reactive on the basis of structure.

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 5000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical.
METHOD	According to the EPA Federal Register, Vol. 50, No. 188, Friday, 27 September 1985.
Species/Strain	Rat/Sprague Dawley.
Vehicle	None.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5/sex	5000	None.
LD50	> 5000 mg/kg bw		
Signs of Toxicity	None.		
Effects in Organs	None.		

CONCLUSION	The notified chemical is of low toxicity via the oral route.
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TEST FACILITY	Pharmakon USA (1993a).
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7.2. Irritation – skin

TEST SUBSTANCE	Notified chemical.
METHOD	Similar to that described in Section 1500.41 – Hazardous Substances and Articles, Administration and Enforcement Regulations, Federal Register, Vol. 38, No. 187, p 27109, 27 September 1973.
Species/Strain	Rabbit/New Zealand White.
Number of Animals	6
Vehicle	None.
Observation Period	72 hours.
Type of Dressing	Occlusive.

RESULTS	No erythema or oedema was observed at 24, 48 or 72 hours after patch removal.
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CONCLUSION	The notified chemical is non-irritating to skin.
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TEST FACILITY	Biosearch (1980).
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7.3. Irritation - eye

TEST SUBSTANCE	Notified chemical.
METHOD	Based on criteria of the Federal Hazardous Substances Act (16 CFR 1500).
Species/Strain	Rabbit/New Zealand White

Number of Animals 6
 Observation Period 72 hours.
 Remarks - Method Undiluted and 50% w/w formulation tested in OS# 75788A (identity not specified).

RESULTS No corneal or iridial effects were seen in any animal at any time point.
 Conjunctival effects were as follows:

Undiluted

Lesion	Mean Score* Animal No.						Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3	4	5	6			
Conjunctiva: redness	1.33	1.67	1.33	1.67	1	0.33	2	72 hours	1
Conjunctiva: chemosis	1.67	1.67	0.33	1	1	0.33	2	72 hours	1
Conjunctiva: discharge	0	0	0	0	0	0	0		0

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

50% w/w dilution

Lesion	Mean Score* Animal No.						Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3	4	5	6			
Conjunctiva: redness	0.33	0.33	0	0.33	0.33	0.33	1	24 hours	0
Conjunctiva: chemosis	0.33	0.33	0.33	0.33	0	0	1		0
Conjunctiva: discharge	0.33	0	0	0.33	0	0	1		0

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

Remarks - Results Yellow sticky material around the eye persisted throughout the study.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1991).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical.

METHOD Maron and Ames (1983): Preincubation assay.

Species/Strain *S. typhimurium*:
 TA1538, TA1535, TA1537, TA98, TA100.
E. coli: WP2 uvrA.

Metabolic Activation System Aroclor 1254 induced rat liver S9 fraction.

Concentration Range in a) With metabolic activation: 0 - 10000 µg/plate.

Main Test b) Without metabolic activation: 0 - 10000 µg/plate.

Vehicle Sesame oil.

Remarks – Method Two independent tests were conducted in triplicate.

RESULTS

Remarks - Results The notified chemical did not induce reproducible increases in induced mutants under the conditions of the tests. Two single observations of a 2-fold increase in mutant numbers in *E. coli*: WP2 uvrA in the presence of S9 at 1670 and 10000 µg/plate were not reproducible in the confirmatory assay and were judged not to represent mutagenicity of the notified

chemical. No toxicity was observed in a preliminary test to 5000 µg/plate and no precipitation was observed.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Pharmakon USA (1993b).

8. ENVIRONMENT

8.1. Environmental fate

The following investigations were conducted using the anhydride of the notified polymer.

8.1.1. Inherent biodegradability

TEST SUBSTANCE	OS25569AY
METHOD	Aerobic Aquatic Biodegradation of Lubricants by the Carbon Dioxide Evolution Test Method.
Inoculum	Activated Sludge and Soil Filtrate Mixtures
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	CO ₂ Evolution
Remarks - Method	Based on procedures specified in the ASTM Standard Test Method D 5864-95, OECD TG 301B CO ₂ Evolution Test, and US EPA Method 796.3260. Pure Wesson canola oil was used a reference substance. Temperature range during test was 18-21°C.

RESULTS

<i>Test substance</i>		<i>Pure Wesson canola oil</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
28	0	28	92%

Remarks - Results The extent of degradation of the reference material validates the test. The test substance showed no degradation throughout the test period.

CONCLUSION The test substance is not readily biodegradable.

TEST FACILITY Wildlife International (1998).

8.2. Ecotoxicological investigations

The following investigations were conducted using the notified polymer (OS#41919M) or the corresponding anhydride (OS#25569) which, when exposed to an aqueous environment, would be expected to hydrolyse to give the notified polymer.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	OS#41919M
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static Conditions.
Species	Rainbow Trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hours
Water Hardness	165 mg CaCO ₃ /L
Remarks – Method	An oil-water dispersion method was used. Water quality parameters of pH, water temperature, O ₂ content were within normal limits throughout study.

RESULTS

<i>Concentration mg/L</i>		<i>Number of Fish</i>	<i>Mortality</i>				
<i>Nominal</i>	<i>Actual</i>		<i>0 h</i>	<i>24 h</i>	<i>48 h</i>	<i>72 h</i>	<i>96 h</i>
0		10	0	0	0	0	0
0.33		10	0	0	0	0	0
3.30		10	0	0	0	0	0
33.0		10	0	0	0	0	2
330.0		10	0	0	0	4	4

3300.0	10	0	0	2	7	9
LC50	917 (95% CL 312-4487) mg/L at 72 hours.					
NOEC	333 (95% CL 109-1251) mg/L at 96 hours.					
Remarks – Results	3.31 mg/L at 96 hours. The analysis is based on nominal amount of test substance added. Undissolved test material was observed at all test levels above 3.3 mg/L, which increased in amount with increasing concentration.					
CONCLUSION	The ecotoxicity data indicate the notified chemical shows some toxicity to fish up to the limit of the water solubility. This may result from a physical effect.					
TEST FACILITY	EnviroSystems Incorporated (1997).					

8.2.2. Algal growth inhibition test

TEST SUBSTANCE	OS#25569
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Freshwater Alga (<i>Selenastrum capricornutum</i>)
Exposure Period	48 hours
Concentration Range	
Nominal	65, 130, 250, 500, 1,000 mg/L
Actual	Test was conducted on the water accommodated fractions (WAFs) prepared from the above nominal test concentrations.
Auxiliary Solvent	None
Water Hardness	Not Specified
RESULTS	
Remarks - Results	Algae were exposed to the WAFs prepared from the anhydride of the notified chemical at a nominal concentration up to 1,000 mg/L under constant illumination and aeration. WAFs were prepared by stirring samples of the test substance with water for 24 h, standing for 4 h and siphoning the water phase through glass wool. When exposed to an aqueous environment it is anticipated that the anhydride would have hydrolysed to yield the notified polymer. After 72 h, there was no significant inhibition of algal growth or biomass at the nominal concentration of 1000 mg/L WAF. Therefore, EC50 > 1,000 mg/L WAF and NOEC is 1,000 mg/L WAF.
CONCLUSION	The ecotoxicity data indicates the notified chemical is practically non-toxic to algae up to the limit of its solubility.
TEST FACILITY	T R Wilbury Laboratories Inc (2000).

8.2.3. Inhibition of microbial activity

TEST SUBSTANCE	OS25569AS
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated Sludge
Exposure Period	3 hours
Concentration Range	
Nominal	1, 10, 100, 1,000, 10,000 mg/L
Remarks – Method	The test was performed on the anhydride of the notified polymer. When exposed to an aqueous environment it is anticipated that the anhydride would have hydrolysed to yield the notified polymer.

RESULTS

IC50

> 10,000 mg/L

NOEC

> 10,000 mg/L

Remarks – Results

The activated sludge study was conducted using sludge obtained from sewage treatment plant in Tennessee, US. The definitive study was conducted as a limit test with a concentration of 10,000 mg/L. The reference material used in the study was 3,5-dichlorophenol. The 3-hour IC50 for the notified substance to activated sludge could not be quantified. However, the 3-hour EC50 for the notified substance to activated sludge is expected to be greater than 10,000 mg/L. The EC50 of the reference substance was 22.0 mg/L, therefore confirming the suitability of the activated sludge.

CONCLUSION

The ecotoxicity data indicates the notified chemical is not toxic to activated sludge up to 10,000 mg/L suspension.

TEST FACILITY

Woodward-Clyde Consultants (1994).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported pre-blended with other components in a diesel fuel additive package. Therefore most of the notified polymer will be burned in the engine along with the diesel fuel. No release to the environment is expected during blending and use, except in the case of accidental spills. Up to 1 tonne per year of the notified polymer could remain in the import containers after emptying.

The notified polymer having both polar and non-polar components will exhibit surfactant properties, and as such is expected to reside at the interfaces between water and oil/organic matter. Spills occurring on land would be expected to be immobile and to remain in the surface soil layer, while spills occurring on water are expected to float on the surface. The containers and any residual product are to be sent to a reconditioning facility, where they are to be cleaned with mineral oil and the residues disposed of by incineration.

The notified polymer will be present in diesel fuels at low levels. Incineration and combustion in engines will produce mainly water vapour and oxides of carbon.

Information on the effects of the notified polymer when blended in fuel with respect to the effect, if any, on emissions of CO₂, NO_x, hydrocarbons, particulates etc was sought from the notifier. This was provided in the form of a technical report (van Helden, 2002), which compared emissions from Ultra Low Sulphur Diesel with fuel containing a quaternary ammonium salt of the notified polymer (Z-47 previously notified as LTD/1040). The tested additive formulation contains 38% of Z-47, compared to ~20% in Lubrizol 539S and is used at <1% in PuriNOx diesel compared with 10 ppm in conventional diesel fuels for the notified polymer.

The test data indicate combustion of PuriNOx containing Z-47 reduced NO_x emission by 14 - 15%, and particulate emissions by 16 - 35% depending on driving conditions (three driving cycles – steady state cycle, European transient cycle, Dutch Urban Bus Cycle). While accompanying these reductions, under all test conditions, emissions of HC increased by about 30% and CO₂ emissions increased by from 1.0 - 1.5%. Emissions of CO increased under steady-state and decreased under dynamic conditions. While the HC emissions rose, they were still well below the Euro 2 standard. The fuel contained 12% water and the consumption of fuel increased by 12%.

Considering the different diesel fuels used, the use of this information as surrogate data for the notified polymer should be treated with caution.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to algae and sewage microorganisms but shows some effects on fish below its water solubility, possibly resulting from a physical effect.

9.1.3. Environment – risk characterisation

No environmental release of the notified polymer is anticipated except in the case of accidental spills. The majority of the polymer will be burnt in engines along with the diesel fuel. Any material lost as a result of spills, or remaining as residues in containers, is expected to be recovered and disposed of by incineration.

There are not enough data to determine if use of the new fuel will have implications for emissions of air pollution or greenhouse gases. However, given that the combustion products arising from the notified polymer comprise only a very small fraction (<< 1.0%) of the total amount of combustion products released by fuel burning itself, the notified polymer is not expected to add significantly to greenhouse gas emissions. The addition of the notified polymer could reduce both NO_x, and particulate emissions while potentially increasing the emissions of HC and slightly increasing CO₂ emissions.

Ecotoxicity endpoints for the notified polymer indicate it is practically non-toxic to algae and bacteria with some effects on fish. The main hazard to organisms arising from the notified polymer would occur in the event of a fuel spill into water, whereby organisms such as birds may become coated with the fuel. However, such spills are expected to be a rare occurrence, and the proposed use pattern is expected to result in negligible exposure to the aquatic environment.

No biodegradation was observed with acclimated sludge within 28 days. Consequently, any material released to the soil or water compartments through accidental spills or leaks would be expected to degrade slowly through bacterial action. Owing to its high molecular weight the polymer is not expected to cross biological membranes and bioaccumulate.

The environmental hazard from the notified polymer is low when it is blended into diesel and used in the manner indicated by the company.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified polymer is not volatile, spills and splashes resulting in dermal and/or ocular contact are the most likely exposure scenario. Exposure is most likely to occur during transfer of the product containing the notified polymer between storage/transport containers and blending facilities, and fuel during the transfer of blended diesel from the blending unit to storage and to subsequent transport, and during the fuelling of vehicles with the blended diesel fuel.

9.2.2. Public health – exposure assessment

Public exposure may occur if there is an accidental spill and/or release of either the fuel additive or the blended diesel fuel. Public exposure to the notified polymer will occur during refuelling of vehicles at petrol stations. Exposure is likely to be by the inhalation and dermal routes, with the possibility of ocular and oral exposure. However, exposure to the notified polymer in fuel will be low as it present at 20 ppm.

9.2.3. Human health - effects assessment

The notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The notified polymer was of low acute oral toxicity in rats ($LD_{50} > 2000$ mg/kg bw), was not a skin irritant and was a slight eye irritant in rabbits and was not mutagenic in bacteria.

9.2.4. Occupational health and safety – risk characterisation

During transport of the additive package, and the blending of the diesel fuel, controls exist to limit occupational exposure to hazardous substances in the product. The MSDS for the product indicates it is harmful if inhaled, causes skin and eye irritation, may cause respiratory tract irritation and may cause chronic health effects. The use of local exhaust ventilation is recommended to control mist and vapours and to maintain the concentration of other ingredients below exposure levels. Personal protective equipment including protective aprons, nitrile gloves, nitrile or neoprene boots and chemical goggles or face shields are recommended.

After blending, the concentration of the notified polymer in the diesel fuel is low. Fuelling of vehicles usually occurs in the open air, and without the use of protective clothing. However, exposure occurs for a period of only a few minutes, and the concentration of the notified polymer in the diesel fuel is low. Due to its low toxicity, and controls in place to prevent exposure to hazardous chemicals in the products in which it occurs, the risk to workers from the notified polymer is expected to be low.

9.2.5. Public health – risk characterisation

As there is not likely to be public exposure to the notified polymer, no characterisation of the risk is required. Exposure during refuelling is expected to be minimal due to the low concentration of the notified polymer in fuel.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

Based on the low toxicity and low potential for aquatic exposure, the notified polymer is not considered to pose a risk to the environment when used in accordance with its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and a product containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for a product containing the chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Protective aprons, nitrile gloves, nitrile or neoprene boots and chemical goggles or face shields.

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of by incineration.

Emergency procedures

- Spills/release of the notified chemical should be soaked up with inert material and placed in labelled containers for recycling or disposal by incineration.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Biosearch Inc (1980) Primary Skin Irritation – Rabbits. OS#25569W. Project No. 80-1872A. Biosearch Inc, PA, USA.

EnviroSystems Incorporated (1997) Static acute toxicity of lubricant additive OS#41919M to the trout, *Oncorhynchus mykiss* - oil-water dispersion study. Study Number 5377, File Reference LUB5377-96-05. EnviroSystems Incorporated NH, USA (unpublished report provided by notifier).

Hill Top Labs (1991) Definitive Eye Irritation Study in Rabbits of: OS# 25569AN. Project No. 90-4325-21(A). Hill Top Biolabs Inc, OH, USA.

Maron D M and Ames B N (1983) Revised Methods for the *Salmonella* Mutagenicity Test. Mutation Res.: 113, 173 – 215.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service: Canberra.

NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service: Canberra.

Pharmakon USA (1993a) Acute Oral Toxicity OS#41919L. Report No. PH 402-LU-032-93. Pharmakon USA, OH, USA (unpublished report provided by notifier).

Pharmakon USA (1993b) Ames/*Salmonella-E. coli* Liquid Preincubation Assay on OS#41919L. Report No. PH 301-LU-103-93. Pharmakon USA, OH, USA (unpublished report provided by notifier).

Safepharma Laboratories Limited (2002) OS 171579: Determination of General Physico-chemical Properties SPL Project Number: 525/436. Safepharma Laboratories Limited, Derby, UK (unpublished report submitted by notifier).

T R Wilbury Laboratories Inc (2000) Acute Toxicity of the Water Accommodated Fraction (WAF) of OS#25569 to the Freshwater Alga, *Selenastrum capricornutum*. Study Number 1906-LU. T R Wilbury Laboratories Inc., MA, USA (unpublished report submitted by notifier).

Wildlife International Ltd (1998) Aerobic Aquatic Biodegradation of Lubricants by the Carbon Dioxide Evolution Test Method; OS69907B, OS12202V, OS16980AL, OS25569AY, OS24925AG, OS43247K. Project No. 331E-107. Wildlife International Inc, OH, USA (unpublished report submitted by notifier).

Van Helden M (2002) Evaluation of PuriNOx Over Steady-State and Transient Test Cycles using a Euro 2 Diesel Engine. Report No. 02.OR.VM.022.1/MvH. TNO Automotive, The Netherlands (unpublished report submitted by notifier).

Woodward-Clyde Consultants (1994) The Effects of Lubrizol OS#25569AS on the Respiration of Activated Sludge (Expanded Range Assessment) WCC INV. #109315 Woodward-Clyde Consultants TN, USA (unpublished report submitted by notifier).