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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Z-92

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-92

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Spectral Data, Methods of Detection and Determination, Molecular Weight, Purity, Identity and % Weight of Impurities, Import Volume, Polymer Constituents, Concentration in the Final End Use Product.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point, Specific Gravity, Vapour Pressure, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA EPA (2008)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-92 (contains 2-30% notified polymer)

MOLECULAR WEIGHT
> 1000 Da

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

3. COMPOSITION

DEGREE OF PURITY > 80%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
In normal use there would be no natural loss of monomers or reactants from the notified polymer.

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: amber viscous liquid (polymer in solvent)

Property	Value	Data Source/Justification
Melting Point	Not determined	Manufactured in solvent.
Density	949 kg/m^3 at 15.6°C	MSDS (Z-92)
Vapour Pressure	Not determined	Expected to be low due to the high molecular weight of the notified polymer. However, low molecular weight species are present.
Water Solubility	Water extractivity (w/w): 91.3% at pH 2 and 65.5% at pH 7.	Water extractivity rather than solubility measured. The notified polymer is predicted to be insoluble in water based on its largely hydrophobic structure. However, it is expected to be surface active and be dispersible in water (by forming micelles), based on both the high tested water extractivity and the cationic nature.
Hydrolysis as a Function of pH	Not determined	No hydrolysable functionalities exist. The notified polymer is not expected to hydrolysis in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	Not determined	The surface active nature of the notified polymer makes it difficult to measure K_{OW}.
Adsorption/Desorption	Not determined	A high value of K_{OC} is expected based on both the mainly hydrophobic structure and the cationic nature of the notified polymer.
Dissociation Constant	Not determined	The notified polymer contains cationic functionality and is expected to be ionised in the environmental pH range 4-9.
Particle Size	Not applicable	Imported in solution.
Flash Point	65°C	MSDS (Z-92)
Autoignition Temperature	Not determined	Manufactured in solvent.
Explosive Properties	Not determined	Not expected to be explosive based on structure.

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer does not have oxidising properties 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

The notified polymer will be imported as 2-30% solution of polymer in solvent in 1041 L ISO containers or 208 L drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	100-300	300-1000	300-1000	300-1000

PORT OF ENTRY
Sydney and other ports

IDENTITY OF RECIPIENTS
Lubrizol International, Inc

TRANSPORTATION AND PACKAGING
Z-92 containing 2-30% of the notified polymer will be imported by sea in 1041 L ISO containers or 208 L drums and transported directly to the fuel manufacturer's refinery terminal for storage. Fully formulated diesel fuel will be delivered to refuelling stations in tank trucks.

USE
The notified polymer is used as a diesel fuel detergent at < 0.1%.

OPERATION DESCRIPTION
Z-92 containing 2-30% of the notified polymer will be transported directly to fuel manufacturer's refinery terminal, and pumped into storage tanks. Later Z-92 is metered into the tank trucks to be mixed with refined fuel to form the fully formulated diesel fuel before delivery to refuelling stations. At the refuelling stations, workers or the public will refill vehicles with the fully formulated diesel containing the notified polymer at < 0.1%.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage of Z-92	15-25	6-8 hours/day	125-225 days/year
Blender	1-2 per site	6-8 hours/day	125-225 days/year
QA analysis	1-2 per site	6-8 hours/day	125-225 days/year
Transport and storage of diesel	15-25	6-8 hours/day	125-225 days/year
End-use fuelling	>10,000	10-30 minutes	200 days/year

EXPOSURE DETAILS
The potential routes of occupational exposure are dermal, ocular and inhalation. However inhalation exposure is not expected as the polymer has low vapour pressure, and the generation of mists/aerosols is not expected.

Transport and storage of Z-92
Transport workers are not expected to be exposed to the imported Z-92 containing the notified polymer at 2-30%, as they will be handling closed containers. Dermal or ocular exposure is possible in the event of an accident where the packaging is breached or during transfer to storage tanks.

Blending
At the fuel manufacturer's refinery terminal, blending of Z-92 with refined diesel fuel is carried out automatically or semi-automatically in a closed system, usually through metering into tank trucks. Exposure to Z-92 may occur from accidental spillage. Exposure is expected to be low and further reduced by workers wearing personal protective equipment when handling diesel fuel.

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

Transport and storage of diesel
Dermal or ocular exposure to drips and spills of diesel fuel containing the notified polymer at < 0.1% is possible during the connection and disconnection of transfer hoses. Exposure is expected to be limited during

transportation as the protocols of loading and unloading are done with minimal spills. The drivers also usually wear gloves and long sleeves shirts when unloading the fuel.

End users of diesel fuel
Personnel from commercial trucking fleet, marine tugs or small ships, agriculture users, railroads, service stations, truck stops and construction companies may be exposed to diesel fuel during handling and fueling of the vehicles. As most of the notified polymer will be combusted with the fuel, exposure is expected to be minimal during end-use/combustion.

6.1.2. Public exposure
The public does not typically have exposure to Z-92 containing the notified polymer at 2-30%.

The public may have incidental skin or eye contact with diesel fuel containing the notified polymer at < 0.1% through operations such as refiling vehicles.

Other exposures to Z-92 or diesel fuel could only occur in the extremely unlikely event of an accident where import containers or the tank trucks are ruptured, liberating Z-92 or diesel containing the notified polymer.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 > 2000 mg/kg bw, low toxicity

Acute toxicity
The notified polymer is of low acute toxicity *via* the oral route.

General toxicity
Systemic toxicity is unlikely as polymers with Mn > 1000 Da are poorly absorbed across biological membranes.

Irritation and Sensitisation
The notified polymer is cationic, which is a structural alert for sensitisation (Barratt, 1994) and irritation (Hulzebos, 2005). Therefore the notified polymer may possess some sensitising and irritant properties.

Health hazard classification
Based on its structure, the notified polymer may have eye and skin irritation and skin sensitisation properties. Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The toxicological properties of the notified polymer have not been fully investigated. However, based on structural alerts, irritancy and sensitisation are possible.

Dermal and ocular exposure will be the main routes of worker exposure to the notified polymer (up to 30% as imported and up to 0.1% in diesel fuel). Exposure is expected to be reduced by various control measures, including engineering controls and PPE already in place for handling diesel fuel. Overall, the risk to workers of the notified polymer is considered to be low.

6.3.2. Public health
The risk to the public from exposure to the notified polymer in diesel fuel is expected to be low based on the low concentrations of the notified polymer in the diesel fuel (< 0.1%) and the expected low exposure to the fuel.

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, and will be imported in Australia in form of diluted solution in isotainers for further formulation at fuel manufacturer's refinery terminal.

At the refinery terminal, the notified polymer will be metered and mixed with refined gasoline to form fully formulated diesel before delivery to refuelling stations. All the operations will be carried out automatically or semi-automatically in a closed system. Therefore, no significant release is expected from the formulation process of the notified polymer. In the event of significant spill, the fuel product containing the notified polymer will be safely cleaned up and is expected to be disposed of to landfill.

The residues in the isotainer is expected to be approximately 1% and will be easily removed by washing with mineral oil and properly disposed of at the container reconditioning facility.

RELEASE OF CHEMICAL FROM USE

At the fuel station, no release is anticipated for normal pumping and distribution of the fuel containing the notified polymer. The spillage at the refuelling station is estimated to be 0.025% for the worst case scenario and would be most likely disposed of to landfill. In automotive engines, the notified polymer will be consumed together with the diesel fuel to generate primarily water and oxides of carbon and nitrogen.

RELEASE OF CHEMICAL FROM DISPOSAL

No significant release of the notified polymer from formulation to end use is expected. Any significant spill would be most likely disposed of to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is not expected to be readily biodegradable based on its structure. Its potential for bioaccumulation is expected to be low based on its molecular weight of > 1000.

Most of the notified polymer will share the fate of the diesel fuel containing it and be consumed in the automotive engines. Residues in containers is not significant and is expected to be removed and treated properly, and most likely will be thermally decomposed to recover the calorific value at the container reconditioning facility. For the limited disposal to landfill, the notified polymer is expected to bind to soil due to the presence of cationic functionality, and undergo slow degradation processes via biotic and abiotic pathways. Either way, the notified polymer will be finally decomposed into small molecules of water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

Calculation of the PEC it is not necessary since the release to environment is predicted to be low based on the reported use pattern of the notified polymer.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer contains cationic functionality which may have toxic effects to the aquatic organisms. However, this is not considered to be of concern considering the limited exposure of the notified polymer to water environment, based on its proposed use pattern.

7.2.1 Predicted No-Effect Concentration

It is not possible to calculate the PNEC for the notified polymer due to the unavailability of the ecotoxicity data for the notified polymer to the aquatic species.

7.3. Environmental risk assessment

It is not possible to calculate the Risk Quotient (PEC/PNEC), since neither the PEC nor the PNEC has been calculated.

The notified polymer may be potentially toxic to the aquatic environment due to the presence of the cationic functionality. However, this will not be a concern given the limited release of the notified polymer to the aquatic ecosystem indicated by the proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is inapplicable as limited toxicity and ecotoxicity data are available.

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

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

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

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 and in the diesel fuel:
  - Coveralls
  - Gloves
  - Safety goggles
  - Respiratory protection if conditions occur where mists are likely to be generated

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

- A copy of the MSDS should be easily accessible to employees.

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

Disposal

- The notified polymer should be disposed of to landfill or be thermally decomposed during container reconditioning.

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 as a diesel fuel detergent at < 0.1%, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1000 tonne per year, 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 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

Water Extractivity 91.3% (w/w) at pH 2 and 65.5% (w/w) at pH 7

Method	OECD TG 120 Water extractability of polymers, final draft version- June 27th, 2007.
Remarks	After sufficient mixing of a certain amount of the notified polymer with water at a loading rate of 10 g/L, the mixture was centrifuged and the total extractable was determined gravimetrically.
Test Facility	Safepharm Laboratories Ltd (2008a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Method. EC Directive 2004/73/EC B.1 *bis* Acute Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley CD strain
Vehicle	None
Remarks - Method	No deviation from the protocol. Following a sighting test at a dose level of 2000 mg/kg, an additional four fasted female animals were given a single oral dose of the undiluted test substance at a dose level of 2000 mg/kg bodyweight.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	1 F	2000	0
2	4 F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no signs of systemic toxicity. All animals showed expected gains in bodyweight.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	There were no deaths.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Safepharm Laboratories Ltd (2008b)

BIBLIOGRAPHY

Barratt, M.D., Basketter, D.A., Chamberlain, M., Payne, M.P., Admans, G.D., Langowski, J.J. (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839.

Hulzebos E, Walker JD, Gerner I and Schlegel K (2005) Use of Structural Alerts to Develop Rules for Identifying Chemical Substances with Skin Irritation or Skin Corrosion Potential. *QSAR Comb. Sci.* 24, 332-342.

NOHSC (1994) 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 (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

Safepharm Laboratories Ltd (2008a) Notified Polymer: Determination of General Physico-chemical Properties, Final Report October 2008, SPL Project Number: 0525/0882 for The Lubrizol Corporation, Wickliffe, OH, USA. Safepharm Laboratories Ltd, Shadlow Business Park, Derbysshire, DE72 2GD, UK (Unpublished report provided by notifier).

Safepharm Laboratories Ltd (2008b) Notified Polymer: Acute Oral Toxicity in the Rat – Fixed Dose Method, Final Report September 2008, SPL Project Number: 0525/0883 for The Lubrizol Corporation, Wickliffe, OH, USA. Safepharm Laboratories Ltd, Shadlow Business Park, Derbysshire, DE72 2GD, UK (Unpublished report provided by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.