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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

RADIASURF 7455

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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 and Energy.

This Public Report is 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

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2060	Robert Wee & Associates	RADIASURF 7455	ND*	< 50 tonnes per annum	Fuel additive

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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

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

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

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 SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000 g/mol;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a fuel additive, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

Safety Data Sheet
The SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Robert Wee & Associates (ABN: 71 899 891 347)
6 Taylor Avenue
LOCKLEYS SA 5032

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

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, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for all physico-chemical endpoints except hydrolysis as a function of pH.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2013)
USA (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME
RADIASURF 7455

MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) is > 1,000 g/mol.

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

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white to light yellow solid

Property	Value	Data Source/Justification
Melting Point	Approx. 59 °C	SDS
Boiling Point	> 250 °C	SDS
Density	Approx. 950 kg/m^3	SDS
Vapour Pressure	1 × 10^{-3} kPa at 20 °C	SDS
Water Solution/Extraction Behaviour	< 20% at 1 g/L and < 2% at 10 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains a functional group that is susceptible to hydrolysis. However due to low water solubility, significant hydrolysis is not expected in the environmental pH range of 4 – 9
Partition Coefficient	log Pow = > 5 (estimated)	SDS

(n-octanol/water)		
Adsorption/Desorption	Not determined	Expected to sorb to sludge, soil and sediment based on its expected limited water solubility and high molecular weight
Dissociation Constant	Not determined	Contains no dissociable groups
Flash Point	> 200 °C	SDS
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	> 300 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported as a component of finished automotive diesel fuel at < 0.01% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 50	< 50

PORT OF ENTRY
Not listed

TRANSPORTATION AND PACKAGING
The introduced diesel fuel (containing the notified polymer at < 0.01% concentration) will be transported from the Australian ports of entry to terminals throughout Australia by pipeline, ship or road tanker. From the terminals the fuels are transferred by road tanker to Australian distributors (mainly service stations). At service stations, the fuel will be transferred from the road tanker to underground storage tanks.

USE
The notified polymer will be used as a diesel fuel additive at < 0.01% concentration.

OPERATION DESCRIPTION
The notified polymer will not be manufactured or reformulated in Australia. The notified polymer will be introduced as a component of finished diesel fuel at < 0.01% concentration. The fuel will be transported to service stations for sale to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
Dermal and ocular exposure to the notified polymer at < 0.01% concentration may occur during transfer of fuel containing the notified polymer from the port of entry to storage tanks at service stations when connecting and disconnecting transfer lines. Given the very low concentration of the notified polymer in the fuel, exposure to the notified polymer will be negligible. Furthermore, exposure is expected to be minimised through the recommended use of appropriate personal protective equipment (PPE) including protective clothing, eye protection and impervious gloves.

Service station workers and mechanics may experience dermal and possibly ocular exposure to the notified polymer at < 0.01% concentration during vehicle maintenance or in the event of a spill. Given the very low concentration of the notified polymer in fuel, exposure to the notified polymer will be negligible.

6.1.2. Public Exposure
The public may experience dermal and possibly ocular exposure to the notified polymer at < 0.01% concentration while pumping fuel containing the notified polymer into fuel tanks at service stations or during vehicle maintenance. Given the very low concentration of the notified polymer in fuel, exposure to the notified polymer will be negligible.

6.2. Human Health Effects Assessment
No toxicity data were submitted.

Based on the high molecular weight of the notified polymer (Mn > 1,000 g/mol) and relatively low levels (< 10%) of low molecular weight species < 500 g/mol, the potential for the notified polymer to cross biological membranes is expected to be limited. Furthermore absorption is expected to be limited by the low water solubility and its estimated high partition coefficient (log Pow = > 5) of the notified polymer. Inhalation exposure of the notified polymer is expected to be low based on its low vapour pressure (1×10^{-3} kPa at 20 °C).

The notified polymer does not contain any structural alerts of concern.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is expected to be of low hazard based on the high molecular weight (Mn > 1000 g/mol) and absence of structural alerts of concern.

Workers may be exposed to the notifier polymer at < 0.01% concentration when handling fuel containing the notified polymer. Given the very low concentration of the notified polymer in fuel, exposure to the notified polymer will be negligible. Furthermore, exposure is expected to be minimised through the recommended use of appropriate PPE including protective clothing, eye protection and impervious gloves.

Therefore, when used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
The public may experience dermal and possibly ocular exposure to the notified chemical at < 0.01% concentration while pumping fuel containing the notified polymer into fuel tanks at service stations or during vehicle maintenance.

Given the very low concentration of the notified polymer in fuel, exposure to the notified polymer will be negligible. Therefore, when used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured or reformulated in Australia. Fuel containing the notified polymer will be transported in closed systems from the port of entry to fuel service stations. Therefore, release of the notified polymer from these activities is not expected.

RELEASE OF CHEMICAL FROM USE

At service stations, the diesel fuel will be pumped through transfer hoses from the underground tank into automobile fuel tanks. Small amounts of notified polymer spilt to the ground are expected to slowly degrade in situ forming water and oxides of carbon. Larger spills will be contained and collected using a suitable adsorbent material within spill kits which are present at service station sites. The collected spills are expected to be disposed of to landfill. No significant release of the notified polymer to the environment is expected during end use because the polymer will be consumed together with the diesel fuel in the automotive engine to generate primarily oxides of carbon and water.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers containing residues of the notified polymer are expected to be refilled with similar chemicals without rinsing or recycled by accredited waste management companies or disposed of according to local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Aliphatic forms of polyethers have been found to have significant potential for biodegradation (Swift, 1997) and will eventually form oxides of carbon and water.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Polymers with low charge density are generally of low concern to the environment. However, repeating units of ethylene oxide (EO) units in the polymer can cause the polymer to become a water dispersible surfactant which can be toxic to aquatic organisms. A portion of the notified polymer has sufficient repeat EO units for this to occur. Most of the notified polymer fraction is not likely to cross biological membranes and bio-accumulate based on its high molecular weight (> 1000 g/mol) and its estimated log Pow of > 5. However, low molecular weight and water extractable species may cross biological membranes and have the potential to bioaccumulate

7.3. Environmental Risk Assessment

When used as intended, the notified polymer will be combusted and will have limited potential for aquatic release. As such, the notified polymer is unlikely to reach concentrations of eco-toxicological concern. Therefore based on its proposed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Solution/Extraction Behaviour < 20% (1 g/L) and < 2% (10 g/L) at 20 °C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water (2000) EC Guideline A.20. Solution/Extraction Behaviour of Polymers in Water (2016)
Remarks	Triplicate samples of test substance at 1 g and 10 g and a blank sample (without the test substance) were weighed into vessels containing 1 L of water. The vessels were agitated for 24 hours at 300 rpm, 20 ± 0.1 °C and filtered through a 0.2 µm filter. The concentration of extractable polymer in the clear aqueous phase was determined by gravimetric analysis.
Test Facility	CRL (2018a)

Hydrolysis as a Function of pH Not determined

Method	OECD TG 111 Hydrolysis as a Function of pH (2004) EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH (2016)
Remarks	The following is from a statement that was submitted by the study authors: The test substance is a complex substance. The best suitable analytical method for such complex substance is Gel Permeation Chromatography (GPC) using Evaporative Light Scattering Detector (ELSD). This analytical method was tested under Test Facility Study No. 20148962. A relation was observed between response and concentration. However, this method was not sensitive enough to measure the test substance in aqueous solutions. It was therefore not possible to develop a sensitive and accurate analytical method to support the hydrolysis study. Furthermore the test substance has low solubility in water, which is demonstrated in Test Facility Study No. 20148961 (the solution/extraction behaviour study).
Test Facility	CRL (2018b)

BIBLIOGRAPHY

CRL (2018a) Determination of the solution/extraction behaviour of [notified polymer] (Test Facility Study No. 20148961, July, 2018). 's-Hertogenbosch, The Netherlands, Charles River Laboratories Den Bosch BV.

CRL (2018b) Determination of the hydrolysis of [notified polymer] as a function of pH, (Test Facility Study No. 20148960, July 2018). 's-Hertogenbosch, The Netherlands, Charles River Laboratories Den Bosch BV.

Swift. G (1997) Environmentally Biodegradable Polymers in Ecological Assessment of Polymers, Strategies for Product Stewardship and Regulatory Programs, pp. 301, Van Nostrand Reinhold.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html