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

PUBLIC REPORT

Polymer in NeoRez R-9330 / NeoRez R-9340

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.

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:

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**Director
NICNAS**

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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
LTD/1886	Reschem Technologies Pty Ltd DIC Australia Pty Ltd	Polymer in NeoRez R9330 / NeoRez R- R9340	ND*	≤ 350 tonnes per annum	Component of industrial inks, coatings and adhesives

*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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an 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 and low expected aquatic exposure, 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.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.
- A copy of the (M)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 containment, physical 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;

or

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

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

(Material) Safety Data Sheet

The (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS

Reschem Technologies Pty Ltd (ABN: 90 315 656 219)
Suite 1103/4 Daydream Street
WARRIEWOOD NSW 2102

DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2144

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume and site of manufacture/reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, China and USA

2. IDENTITY OF CHEMICAL

MARKETING NAMES

NeoRez R-9330 (product containing the notified polymer)
NeoRez R-9340 (product containing the notified polymer)

MOLECULAR WEIGHT

> 10,000 Da

ANALYTICAL DATA

Reference GPC data was provided.

3. COMPOSITION

DEGREE OF PURITY

$\geq 95\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be introduced in a liquid product
Boiling Point	Not determined	-
Density	Not determined	-
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer, the vapour pressure is expected to be low
Water Solubility	Dispersible	(M)SDS; the notified polymer will be introduced in an aqueous medium

Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to rapidly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Not expected to be high, based on dispersibility and ionic properties
Adsorption/Desorption	Not determined	Expected to partition to soil and sediment based on high molecular weight and ionic properties
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply explosive properties

DISCUSSION OF PROPERTIES

Reactivity

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

Physical hazard classification

Based on the available information on physico-chemical properties, 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 in to Australia in bulk as part of formulations, or in end-use products.

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

Year	1	2	3	4	5
Tonnes	≤ 350	≤ 350	≤ 350	≤ 350	≤ 350

PORT OF ENTRY

Adelaide, Brisbane, Melbourne, Perth and Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be imported at ≤ 50% concentration in intermediate bulk container (IBC) and plastic drums. The notified polymer will also be imported in end-use products such as inks, adhesives and coatings in metal containers of various sizes ranging from 22.6 kg to 226 kg.

USE

The notified polymer will be used in industrial inks including flexographic inks at ≤ 10% concentration and in coatings and adhesives at concentrations ≤ 20%.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. It will be imported in bulk for reformulation, and in end-use products.

For reformulation into inks, coatings or adhesives, the notified polymer in bulk at the site of reformulation will be transferred from the container into the blending equipment either with the aid of metering pump through a vacuum hose line, or using a semi-automated process. Samples will be collected from sampling port during and after blending for quality control. After blending, the end-use products containing the notified polymer will be transferred to 1 to 20 L containers via an automated and metered process. The products will be supplied to Australian industrial customers.

During end-use of the products containing the notified polymer, they may be applied to substrates by spray, brush, roller or dispensers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Stevedores	1	5
Transport and warehouse workers	1	5
Reformulation process workers	4	260
Quality control workers	4	260
Maintenance, shift workers and cleaners at reformulation site	1	260
Workers at industrial and end-use sites	4	260
Maintenance, shift workers and cleaners at end-use site	1	260

EXPOSURE DETAILS

Transport and Storage

Stevedores, transport and warehouse workers will handle the notified polymer at up to 50% concentration in containers of various sizes ranging from 22 L to 1,000 L. Exposure of these workers will be limited to events where there is a discharge, spill or leakage from damaged containers. If such an event occurs, a worker may be exposed to the notified polymer through dermal or ocular contact.

Reformulation

Reformulation and quality control workers may be exposed to the notified polymer at up to 50% concentration via the dermal and ocular route during the transfer of the polymer for reformulation, sampling for quality control and packaging of reformulated products. Cleaning and maintenance workers may also be exposed to the notified polymer during the cleaning and maintenance of blending equipment.

End-use

The final products containing the notified polymer at up to 20% concentrations will be used in printing including flexographic printing, coatings and adhesives.

Workers in the printing industry handling the inks containing the notified polymer ($\leq 10\%$ concentration) may be exposed via the dermal route and perhaps accidentally via ocular route during the addition of ink, attending to substrate jams or during the cleaning and maintenance of printing machines. Inhalation exposure is not anticipated due to the process being carried out in enclosed system with local exhaust ventilation.

When used in adhesives or coatings, the workers handling the products containing the notified polymer ($\leq 20\%$ concentration) may be exposed via the dermal, ocular or inhalation route during the application of the product on various surfaces. The products will be applied by spray, brush or roller. Spray application will normally be carried out in closed spray booths by manual or automated means.

Exposure to the notified polymer during handling, reformulation and end-use is proposed to be minimised by the use of engineering controls such as enclosed systems and exhaust ventilation and by personal protective equipment (PPE) including impervious gloves, coveralls, safety glasses and respiratory protection if required.

6.1.2. Public Exposure

The public may come into contact with the dried printed or coated surfaces containing the notified polymer. However, once the inks and surface coatings have dried, the notified polymer will be bound within a polymer matrix and is not expected to be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a high molecular weight (> 10,000 Da) and very low percentage of low molecular weight species; hence absorption across biological membranes is expected to be limited. Based on its structure, the potential for irritation cannot be ruled out.

High molecular weight water insoluble polymers have the potential for lung overloading. The water solubility of the notified polymer is not known, but is expected to be low. The risk to workers during spray application would be minimised by compliance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Dermal and ocular exposure to the notified polymer may occur during transport, storage, reformulation and end-use of products containing the notified polymer. Inhalation exposure is not anticipated due to proposed engineering controls including closed systems and exhaust ventilation. The use of PPE including impervious gloves, safety glasses and coveralls by workers will further reduce exposure to the notified polymer. Overall, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will not be available to the public, except after the product has been applied and cured and the notified polymer becomes bound within a polymer matrix. The notified polymer is not expected to be bioavailable, hence the risk to the public is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of a solution for reformulation into finished industrial printing inks, coatings and adhesives. During reformulation, the solution containing the notified polymer will be transferred into a closed blending tank using metering pumps, and mixed with other ingredients to produce finished printing inks, coatings and adhesives. Finished printing inks, coatings and adhesives will be automatically dispensed into packaging. Environmental release of the notified polymer during reformulation and repackaging is expected to be limited to accidental spills and leaks. In the event of accidental spills or leaks, the notified polymer will be contained and collected with absorbents, and is expected to be disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

Printing inks containing the notified polymer will only be used within industrial settings, and are expected to be printed onto non-recyclable substrates including plastics. Once printing is complete, the notified polymer is expected to be irreversibly bound within an inert ink matrix, and is not expected to be released from the printed articles. The printing process will be largely automated; therefore, release of the ink containing the notified polymer to the environment is expected to be limited to accidental spills and leaks. Wastes containing the notified polymer due to equipment cleaning or spillages are expected to be disposed of to landfill in accordance with local government regulations.

Coatings and adhesives containing the notified polymer will only be used within industrial settings, and are expected to be applied to a variety of substrates including concrete, timber, glass, plastics and wood. Coatings will be applied using spray, brush, or roller techniques, and adhesives will be applied using spray, roller or dipping techniques. Any losses from overspray during application of coatings and adhesives (estimated by the

notifier to be < 20% of the annual import volume) are expected to be collected. All wastes generated during use including container residue and equipment washing are expected to be allowed to cure, then disposed of in accordance with local government regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will share the fate of the articles to which it is applied. Printed articles are expected to be disposed of to landfill at the end of their useful life; coated or adhered articles are expected to be disposed of to landfill, or undergo substrate reclamation. During substrate reclamation, the notified polymer is expected to be thermally decomposed. Residue inks, coatings and adhesives containing the notified polymer in empty containers are expected to be disposed of to landfill in accordance with local government regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. Since the notified polymer has a molecular weight much greater than 1,000 Da with no significant percentage of low molecular weight constituents, it is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate.

The majority of the notified polymer is expected to be bound within an inert polymer film on printed and coated articles, or within an inert polymer matrix in adhered articles following application. The notified polymer will therefore share the fate of the articles to which it is bound, and is expected to be ultimately disposed of to landfill in the majority of cases. The notified polymer is likely to adsorb strongly to soil and sediment due to its high molecular weight and ionic properties, and is not expected to be mobile within the environment. In landfill, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated, since no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Ecotoxicological endpoints for aquatic organisms for the notified polymer were calculated based on structure-activity relationship (SAR) equations, assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
<u><i>Acute Toxicity</i></u>		
Fish	96 h LC50 = 76.53 mg/L	Predicted to be harmful to fish
Daphnia	48 h EC50 = 12019.16 mg/L	Not predicted to be harmful to <i>Daphnia</i>
Algae	96 h EC50 = 353.66 mg/L	Not predicted to be harmful to algae
<u><i>Chronic Toxicity</i></u>		
Fish	ChV = 4.25 mg/L	Not predicted to be harmful to fish in the long term
Daphnia	ChV = 667.73 mg/L	Not predicted to be harmful to <i>Daphnia</i> in the long term
Algae	ChV = 83.59 mg/L	Not predicted to be harmful to algae in the long term

Based on the above worst case SAR estimations, the notified polymer is expected to be acutely harmful to fish, but is not expected to be harmful to daphnia and algae. The SAR estimation procedure used here is a standard approach, and is considered reliable to provide general indications of the likely environmental effects of the polymer for the purposes of risk assessment. However, this method is not considered sufficient to formally classify the acute and chronic hazards of the notified polymer to aquatic life under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive acute endpoint for fish. A safety factor of 500 was used given no empirical data are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	76.53	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	153.06	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) of the notified polymer has not been calculated as the PEC is not available, and due to its low potential for release to the aquatic compartment. The majority of the notified polymer will be irreversibly bound to printed, coated and adhered articles, and after their useful lives, share the fate of the articles to which it is applied. Based on its high molecular weight and ionic properties, the notified polymer is not expected to be bioaccumulative. Therefore, on the basis of its limited aquatic exposure, maximum annual importation volume, and assessed use pattern in industrial printing inks, coatings and adhesives, the notified polymer is not expected to pose an unreasonable risk to the environment.

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