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

PUBLIC REPORT

Polymer in NeoRad P-60

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
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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/1776	Reschem Technologies Pty Ltd	Polymer in NeoRad P60	ND*	≤ 300 tonnes per annum	Component of industrial printing inks

*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 for the 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

Provided that the recommended PPE is used and engineering controls are in place to limit exposure, 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Health Surveillance

- As the notified polymer is a potential sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed automated processes, where possible
 - Local exhaust ventilation where inhalation exposure may occur
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with skin and eyes
 - Avoid inhalation of aerosols
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Safety glasses

- Impervious gloves
- Coveralls

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

- 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 for the 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 available or practical, dispose of the polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment with non-combustible absorbent material, 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(2) of the Act; if
 - the function or use of the polymer has changed from component of printer ink 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer provided by the notifier was 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

APPLICANT(S)

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

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physicochemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

China
Taiwan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

NeoRad P60 (imported product containing the notified polymer at < 65% concentration)

MOLECULAR WEIGHT

$M_n > 1,000$ Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 20 °C	Estimated
Density*	1,100 kg/m ³ at 25 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Expected to have low water solubility based on its predominantly hydrophobic structure.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities, however, significant hydrolysis is not expected to occur under normal environmental conditions (pH 4 – 9).

Property	Value	Data Source/Justification
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition from water to n-octanol due to its expected low water solubility.
Adsorption/Desorption	1.07×10^{-25}	Calculated (using KOCWIN v2.00; US EPA, 2009)
Dissociation Constant	Not determined	Does not contain any readily dissociable functionality.
Flash Point*	> 100 °C	(M)SDS
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	Not determined	Not expected to autoignite at ambient temperature and during normal use.
Explosive Properties	Not determined	Not expected to be explosive based on chemical structure.
Oxidising Properties	Not determined	Not expected to be oxidising based on chemical structure.

* For the imported product NeoRad P-60 containing the notified polymer at < 65% concentration.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of storage and polymerises under conditions of heat and light. The notified polymer is intended to react in end-use products through UV curing.

Physical hazard classification

Based on the available information, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the 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 be imported into Australia as a liquid solution at < 65% concentration or as a component of a pigment paste at < 25% concentration.

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

Year	1	2	3	4	5
Tonnes	< 300	< 300	< 300	< 300	< 300

PORT OF ENTRY

Brisbane, Melbourne and Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a liquid solution (containing the notified polymer at < 65% concentration) or as a pigment paste (containing the notified polymer at < 25% concentration) in 200 kg drums. The notified polymer solution may be reformulated into pigment paste (containing the notified polymer at < 25% concentration), or into liquid inks (containing the notified polymer at < 35% concentration). Pigment paste containing the notified polymer (at < 25% concentration) will be reformulated into paste-like inks containing the notified polymer at < 15% concentration. The finished products (liquid inks and paste-like inks) will be packaged in plastic or metallic containers between 1 and 25 kg in size for distribution to end-users by road.

USE

The notified polymer will be used as a component of printing inks at < 35% concentration for use in screen printing applications on flexible substrates and paper.

OPERATION DESCRIPTION

Reformulation

The notified polymer will be imported as a liquid solution (containing the notified polymer at < 65% concentration) or as a pigment paste (containing the notified polymer at < 25% concentration) for reformulation

in Australia. At the reformulation sites the product containing the notified polymer will be directly transferred from the import containers to a closed mixing tank and mixed with other ingredients. Once the reformulation is complete, an automated and metered process will be used for filtration and filling of the printing ink (containing the notified polymer at a concentration of < 35%) into containers. Quality control personnel may sample the final printing ink containing the notified polymer (at < 35% concentration).

End use

In closed or open screen printing presses, ink (containing the notified polymer at < 35% concentration) will be manually loaded into the ink tray, with the transfer of ink from the tray to the press being automated. In both printing processes, the substrate is automatically moved between print stations containing the different coloured inks. At each station, the ink is cured with UV light following application to the substrate. The substrate is then transferred to the next printing station and the next colour ink is applied. The substrate is stacked at the end of the printing line. In an open system, the screens are installed manually. After operation, the screens are then removed for cleaning in a separate area.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS

Waterside, storage and transport workers may come into contact with the notified polymer at < 65% concentration, only in the unlikely event of accidental rupture of containers.

Reformulation will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified polymer at up to 65% concentration when connecting and disconnecting transfer hoses, during quality control testing and maintenance and cleaning tasks. Dermal and ocular exposure to workers should be mitigated through the stated use by the notifier of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected unless aerosols are formed as the notified polymer is expected to have a low vapour pressure at ambient temperatures. Inhalation exposure to aerosols of the notified polymer should be minimised through the use of local exhaust ventilation and enclosed processes.

Screen print operators may be exposed (dermal and ocular) to the finished ink products containing the notified polymer at < 35% concentration when loading ink into the ink trays and when handling print screens which have been in contact with the ink. Exposure to screen print operators should be mitigated through the stated use by the notifier of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure to aerosols of the notified polymer should be minimised through the use of local exhaust ventilation and enclosed processes.

6.1.2. Public Exposure

The finished ink products containing the notified polymer at < 35% concentration are intended for industrial use and will not be available to the public. Once the ink is cured and dried, the notified polymer will be part of an inert matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

The notified polymer is not expected to be absorbed across biological membranes to a significant extent based on its high molecular weight ($M_n > 1000$ Da). However, the polymer contains a relatively high percentage of low molecular weight species (< 1,000 Da) that may be absorbed.

The notified polymer contains the acrylate functional group which is a potential concern for irritation and sensitisation (US EPA, 2010). However the risk of irritation and sensitisation may be limited by the high molecular weight of the notified polymer.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the 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**

Based on the presence of acrylate functional groups, the notified polymer may be a potential irritant and sensitiser.

Reformulation workers may be at risk of irritating and sensitising effects when handling the notified polymer at up to 65% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes and the use of PPE including coveralls, impervious gloves and goggles. Inhalation exposure by reformulation workers to the notified polymer is not expected as the vapour pressure of the notified polymer at ambient temperatures is predicted to be low and the largely enclosed processes reduce the potential for exposure to aerosols. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

Screen printing operators will also be at risk of irritating and sensitising effects when handling the formulated inks containing the notified polymer at up to 35% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes, and the use of PPE including coveralls, impervious gloves and goggles. Inhalation exposure by printer operators to the notified polymer is not expected as the vapour pressure of the notified polymer at ambient temperatures is predicted to be low. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of printer operators is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will be used in industrial settings only and will not be sold to the public. The public may come into contact with the printed articles containing the notified polymer. However, once the notified polymer is cured, it will be bound within a polymer matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

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 in Australia. However, the notified polymer will be imported into Australia as a raw material for local reformulation of inks. During reformulation, spills and leaks are expected to be collected using suitable absorbent materials and placed in closed containers for disposal to landfill. Empty containers are likely to be disposed of to landfill. Residues in the empty containers and waste water from equipment washings are expected to be collected and disposed of to a liquid waste facility. The notified polymer is not expected to be released to sewers during reformulation.

RELEASE OF CHEMICAL FROM USE

The majority of the release of the notified polymer to the environment from use will be from ink spills, wash-downs of printing equipment and from disposal of empty containers containing residual ink. The notified polymer will be UV-cured (chemically reacted) and it is expected to be stable within an inert matrix on printed substrates once it is cured.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer will be used in ink for printing on paper. The notified polymer is expected to share the fate of the printed articles which are expected to be disposed of to landfill. It is assumed that 50% of the printed paper will end up in landfill and the rest will undergo paper recycling processes. Empty containers containing residues of the notified polymer (up to 0.5% of the total import volume) are expected to be disposed of to landfill. Hence, the majority of the total import volume of the notified polymer is expected to be disposed of to landfill with a potential for some release to sewer.

7.1.2. Environmental Fate

No environmental fate studies were submitted. Approximately half of the paper to which the ink containing the notified polymer is applied to is likely to be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. However, the notified polymer will be UV/EB cured (chemically reacted) into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified polymer is anticipated to partition to sludge and sediment. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The notified polymer is not expected to bioaccumulate due to its high molecular weight. Notified polymer applied to substrates will be UV/EB cured (chemically reacted) and is not expected to be bioavailable. The majority of the cured notified polymer is expected to be disposed of to landfill where it is anticipated to degrade by biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in printing, it is conservatively assumed that 100% of the total import volume of the notified polymer will be used in paper printing. Using a worst-case scenario, it is assumed that 50% of the paper products containing the notified polymer will be recycled and will be released to the sewer with no removal during recycling or STP processes. As the notified polymer is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days per year into the Australian effluent volume. The resultant estimate for the predicted environmental concentration (PEC) in sewage effluent nationwide is summarised in the table below.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	300,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	150,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	576.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	127.57	µg/L
PEC - Ocean:	12.76	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 127 µg/L may potentially result in a soil concentration of approximately 0.85 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 4.2 mg/kg and 8.5 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. The notified polymer is a non-ionic polymer which is generally of low concern to the environment. Therefore, the notified polymer has not been formally classified for its acute and long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated as ecotoxicity data for the notified polymer were not available. The notified polymer is not expected to be readily bioavailable and is predicted to have no significant effect on aquatic biota.

7.3. Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the notified polymer was not calculated as a PNEC was not derived. Release of the notified polymer to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The notified polymer is not expected to be bioaccumulative and is expected to slowly degrade in the environment. Based on the assumed low hazard and the assessed use pattern of the notified polymer, it is not expected to pose an unreasonable risk to the environment.

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