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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Neorad P50

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 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

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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/1855	Flint Group Australia Pty Ltd Reschem Technologies Pty Ltd	Polymer in Neorad P50	ND*	< 5 tonnes per annum	Component of industrial printing ink

*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
Provided that the recommended controls are in place to limit exposure, 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 PEC/PNEC ratio and 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

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls where possible to minimise occupational exposure to the notified polymer;
  - Enclosed, automated processes
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer;
  - Avoid contact with skin and eyes
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment promptly

- 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;
  - Coveralls
  - Impervious gloves
  - Goggles
  - Respiratory protection if inhalation exposure may occur

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 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 Da;
- further information becomes available on the sensitisation potential of the notified polymer.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of industrial printing 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.

(Material) Safety Data Sheet
The (M)SDSs of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicants.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Flint Group Australia Pty Ltd (ABN: 79 006 659 178)
23 Seton Rd
MOOREBANK NSW 2170

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual monomers and impurities, additives/adjuvants

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
USA (2015), Canada, China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Neorad P50 (imported product containing the notified polymer at ≤ 75% concentration)

OTHER NAME(S)
Neorad P50 XP

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 60%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at room temperature
Boiling Point	> 100 °C at 101.3 kPa	(M)SDS
Density	1,110 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on its high molecular weight

Water Solubility	Insoluble	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to hydrolyse under environmental conditions based on low water solubility.
Partition Coefficient (n-octanol/water)	log Pow = 2.5 approximately	Analogue data
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on high molecular weight, low water solubility, and potential cationic properties.
Dissociation Constant	Not determined	Contains potentially cationic functionalities; however, not expected to be ionised under environmental conditions (pH 4-9) based on low water solubility.
Flash Point	> 100 °C	(M)SDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to be self-igniting
Explosive Properties	Not explosive	Contains no explosophores that would imply explosive properties.
Oxidising Properties	Not oxidising	Contains no functional groups that imply oxidative properties.

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is intended to react under 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 be imported into Australia in solution at ≤ 75% concentration or as a component of a pigment dispersion/paste at ≤ 40% concentration.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200 kg metal drums, which will be transported by road to the customer site for reformulation. The finished ink products containing the notified polymer at ≤ 20% will be packaged in 5 kg bottles or 10 kg plastic buckets for distribution to end-users by road.

USE
The notified polymer will be used as a component of printing inks at ≤ 20% concentration on vinyl, canvas, plastic packaging and paper.

OPERATION DESCRIPTION
The notified polymer will not be manufactured within Australia, but the imported solution (containing the notified polymer at ≤ 75% concentration) or pigment dispersion/paste (containing the notified polymer at ≤ 40% concentration) will be reformulated.

Reformulation

At the reformulation sites the product containing the notified polymer will be directly transferred from the import containers via a metering pump to a closed mixing tank and blended 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 ≤ 20%) into containers. Quality control personnel may sample the final printing ink containing the notified polymer (at ≤ 20% concentration).

End use
Ink bottles (containing the notified polymer at ≤ 20% concentration) will be manually connected to the printing machines and the inks, then automatically injected into printing machines. After printing, the notified polymer will be ultra violet (UV) or electron beam (EB) cured with other ink ingredients onto the substrate.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Stevedores	2-3	5
Transport and warehousing/storage	4-8	5
Blending operators	8	260
Quality control workers	0.5-6	260
Maintenance, shift workers and cleaners at reformulation site	8	260
Wholesale printer suppliers	8	260
Printer operators	1-2	260
Service technician	8	260
Maintenance, shift workers and cleaners at printing site	8	260

EXPOSURE DETAILS
Waterside, storage and transport workers may come into contact with the notified polymer at ≤ 75% concentration, only in the unlikely event of accidental rupture of containers.

Reformulation processes will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified polymer at ≤ 75% 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.

Printing operators may be exposed (dermal and ocular) to the finished ink products containing the notified polymer at ≤ 20% concentration when manually connecting to the printing machine, replacing ink bottles, during colour matching and quality control processes, and during maintenance and service tasks. Exposure to printer operators should be mitigated through the stated use 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.

After application to the substrate and curing, the ink containing the notified polymer will be part of an inert matrix, and hence no longer available for exposure

6.1.2. Public Exposure
The imported product containing the notified polymer at ≤ 75% and finished ink products containing the notified polymer at ≤ 20% 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.

Absorption of the notified polymer across biological membranes (gastrointestinal tract and skin) would be limited by its high molecular weight (>1000 Da) and low water solubility. However, the notified polymer contains a proportion of low molecular weight species which may be absorbed.

Irritation and sensitisation
The notified polymer contains acrylate functional groups that have been associated with irritation and skin sensitisation effects (US EPA, 2010). However the risk of irritation and sensitisation may be limited by the high molecular weight of the notified polymer.

No data has been provided on eye, skin or respiratory irritation, and the potential for these effects cannot be ruled out. It is noted that a European industry guide (Cefic, 2011) recommends classification of polymeric acrylates for eye and skin irritation in the absence of data on these endpoints.

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
Based on the structure, the notified polymer may cause skin sensitisation and may have potential for skin, eye and respiratory irritation.

Exposure and risk to reformulation workers using the notified polymer at ≤ 75% is expected to be limited by the use of engineering controls (local ventilation, largely automated and enclosed processes) and the use of PPE including coveralls, impervious gloves, safety glasses, safety boots, and respirator if required. Inhalation exposure by workers to the notified polymer would be reduced as the vapour pressure of the notified polymer at ambient temperature is predicted to be low, and the largely enclosed processes reduce the potential for exposure to aerosols.

Printer operators might also be at risk of irritating and sensitising effects when handling the formulated inks containing the notified polymer at ≤ 20% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes, exhaust ventilation and the use of PPE including coveralls, impervious gloves and goggles. Exposure of the service technicians to the notified polymer is also expected to be limited by the use of PPE including goggles and gloves. Safe work practices would further reduce worker exposure and risk.

The controls in place to reduce exposure to the hazardous ingredient present in the product mixture would also reduce worker exposure to the notified polymer.

Therefore, provided that engineering controls are in place to limit exposure where available, the stated PPE is used and safe work practices are implemented, the risk posed to occupational health and safety of workers 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 products containing the notified polymer. However, once the notified polymer is cured, it will be bound within the ink 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 be imported into Australia as a component of a solution and a pigment dispersion/paste for reformulation into finished UV/EB-cured flexographic printing inks. During reformulation, the notified polymer in the solution and pigment dispersion/paste will be transferred into a closed blending tank using metering pumps, and mixed with other ingredients to produce finished printing inks. Finished printing inks will be automatically dispensed into end-use packaging. Environmental release of the notified polymer during reformulation and repackaging is expected to be limited to accidental spills and leaks.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used as a component of UV/EB-cured printing inks for flexographic printing onto vinyl, canvas and plastic substrates. A minor amount of ink containing the notified polymer (≤ 20% of the annual import volume, or 1,000 kg) will be used for printing onto paper substrates. Printing will be largely enclosed and automated. The notified polymer is expected to be stable within an inert ink matrix on printed substrates once UV/EB-cured (chemically reacted).

Potential environmental release of the notified polymer during use is expected to be limited to accidental spills and leaks, ink colour matching processes, and cleaning of printing equipment. It is estimated by the notifier that up to 3% of the annual import volume of the notified polymer (or 150 kg) may be released to sewer from ink colour matching and equipment washing during use. Spills and leaks will be contained and collected with absorbents, and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer will be used in UV/EB-cured printing ink for printing onto vinyl, canvas, plastic, and paper substrates. The majority of the notified polymer is expected to share the fate of the printed articles to which it is bound, and is expected to be disposed of to landfill at the end of their useful lives.

Of the 20% import volume applied to paper, it is assumed that half of this amount is expected to be disposed of to landfill, and the remainder will undergo paper recycling processes. Empty ink containers containing residues of the notified polymer are expected to be disposed of to landfill. Hence, the majority of the notified polymer is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified polymer will be released to sewer.

7.1.2. Environmental Fate
No environmental fate data was submitted for the notified polymer. The notified polymer in printing ink applied to substrates will be UV/EB cured (chemically reacted) into an inert ink matrix, and is expected to remain adhered to the printed articles throughout its useful life and not be mobile, bioavailable or bioaccumulative in this form. The notified polymer will share the fate of the printed articles, which will involve eventual disposal to landfill. The notified polymer in solid wastes disposed of to landfill is not likely to be mobile or bioavailable due to its high molecular weight and limited water solubility.

Approximately 50% of the paper substrates to which the ink containing the notified polymer is applied are expected to be recycled. During the de-inking process, the UV/EB cured ink containing the notified polymer is unlikely to be released into the supernatant waters. Based on its molecular weight and potentially cationic properties, up to 90% of the cured ink containing the notified polymer is expected to adsorb to sludge and sediment (Boethling and Nabholz, 1997), with the sludge eventually disposed of to landfill or re-used for soil remediation.

Based on its molecular structure, the notified polymer contains biodegradable functionalities, and is expected to be biodegradable. Bioaccumulation of the uncured notified polymer is not likely as it is not expected to cross biological membranes due to its high molecular weight and low water solubility. The notified polymer in landfill 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 been calculated based on volume of the notified polymer to be applied to paper substrates (20%) and to be released to sewer during reformulation processes (3%). It is expected that half of the paper products containing the notified polymer undergoing recycling (i.e. 10% of the import volume). The PEC has been calculated to assume a worst case scenario, with no removal during recycling

or STP processes when released to sewers. As reformulation of the notified polymer and paper recycling are to be processed at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	13%	
Annual quantity of chemical released to sewer	650	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	2.50	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:	0.553	µg/L
PEC - Ocean:	0.055	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.553 µg/L may potentially result in a soil concentration of approximately 3.685 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 18.43 µg/kg and 36.85 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. The notified polymer in its uncured form contains reactive functional groups which may be toxic to aquatic organisms. However, based on its high molecular weight and low water solubility, the notified polymer is not expected to be bioavailable or bioaccumulative. Ecotoxicity values were provided for fish, Daphnia and algae on an analogue which is expected to be of higher ecotoxity than the notified polymer. The full study reports were not submitted. The highest toxicity observed was > 5 mg/L, in fish. The analogue data is not considered sufficient to formally classify the hazard 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

An indicative no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for fish. Acute endpoints for three trophic levels are available; however, as the full study reports have not been submitted, a safety factor of 500 was used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	> 5	mg/L
Assessment Factor	500	
Mitigation Factor	1.00	
PNEC:	> 10	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.553	> 10	< 0.055
Q - Ocean	0.055	> 10	< 0.006

The estimated Risk Quotients for discharge of treated effluents containing the notified polymer to the aquatic environment indicate that the notified polymer is unlikely to reach ecotoxicologically significant concentrations

in surface waters, based on its maximum annual importation quantity and proposed usage pattern. The notified polymer is expected to be biodegradable and is expected to have a low potential for bioaccumulation, based on its high molecular weight and low water solubility. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in printing ink, the notified polymer is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

Boethling, RS, Nabholz, JV (1997). "Environmental Assessment of Polymers under the US Toxic Substances Control Act", in: Hamilton, JD, Sutcliffe, R (ed). Ecological Assessment of Polymers: Strategies for product stewardship and regulatory programs. Van Nostrand Reinhold, New York.

Cefic (2011) Guide to the Classification and Labelling of Acrylates, 4th edition. European Chemical Industry Council (CEFIC), Brussels, Belgium, UV/EB Acrylate Resin Sector Group, http://www.cefic.org/Documents/Industry%20sectors/UVEB/Guide-to-the-Classification-and-Labelling-of-UV-EB-Acrylates.pdf

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

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 >.

US EPA (2010), TSCA New Chemicals Program (NCP) Chemical categories, Washington, D.C., http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf