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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in NeoCryl XK-30

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
ResChem Technologies (ABN 90 315 656 219)
5/56 Kalang Road,
Elanora Heights
NSW 2101

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, CAS number, Molecular and structural formulae, Molecular weight, Analytical data, Polymer constituents, Residual monomers, Impurities, and Use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting point/Freezing point, Boiling point, Density, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient, Dissociation constant, Particle size, Flash point, Flammability limits, Autoignition temperature, Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NeoCryl XK-30 (product containing the notified polymer at <40%)

Mn Value >10,000 Da

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >98%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is expected to be stable under normal conditions.

DEGRADATION PRODUCTS
The notified polymer is not expected to degrade under normal conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White slightly yellow liquid (for the imported product)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced as an aqueous solution
Boiling Point	100°C at 101.3 kPa	For the imported product
Density	1.05 kg/m^3 at 20°C	For the imported product
Vapour Pressure	20 kPa at 25°C	For the imported product
Water Solubility	Not determined	The notified polymer is expected to be miscible in water, based on its structure and use in aqueous products
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable groups, but the rate of hydrolysis is expected to be slow in the environmental pH range (4–9)
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer may partition from water into octanol, based on the presence of hydrophobic groups in the polymer
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil, based on its high molecular weight and presence of potentially cationic functionality, which will bind the polymer to soil and sediment
Dissociation Constant	Not determined	The notified polymer will likely be ionised in the environmental pH range due to the presence of a basic function in the polymer
Particle Size	Not determined	Introduced as an aqueous solution
Flash Point	Not determined	MW >10,000 Da
Flammability	Not determined	Based on chemical structure, the notified polymer is not expected to be flammable
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Not expected to have explosive properties

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

Reactivity
The notified polymer is stable under normal conditions.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table, the notified polymer is not classified as hazardous according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

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 and will be imported as an aqueous solution, at a concentration of <40%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	200	200	200	200	200

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
ResChem Technologies
5/56 Kalang Road, Elanora Heights, NSW 2101

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 205L drums and 1000L containers and transported by road from the dockside to the notifier's site for storage. The notified polymer solution will be further transported by road and rail to several sites around Australia for formulation into coatings.

USE
The notified polymer will be used as a component of coatings and paint (<30%) for both industrial and DIY uses.

OPERATION DESCRIPTION
The product containing the notified polymer at <40% concentration will be imported and transported from the dockside to the notifier's site for storage and for further transportation to several sites around Australia for reformulation into coatings.

At the coating manufacturer, the product containing the notified polymer at <40% concentration would be typically pumped into a closed mixing vessel, to which other coating components would be added. The product in the mixing vessel would be blended using mechanical agitators under local exhaust ventilation to capture volatiles at source. Following dispersion, the coating (containing the notified polymer at <30%) would be pumped through automated filling lines for packaging. Transfer and packaging processes are automated and enclosed. The end use product is supplied in multiple container sizes including 1L, 2L, 4L, 10L, and 20L.

Laboratory technicians will also be involved in performing quality control tests on the coating formulation. Maintenance and cleaning of equipment used in blending the coating will occur on a regular basis. In this regard, the application equipment is expected to be washed using industrial solvent (such as mineral spirit) and disposed of via licensed waste contractors.

For end use applications, coatings containing the notified polymer (<30%) will be applied by spray (~75%), roller (~15%) or brush (~10%). Spray applications will be conducted in spray booths located at industrial manufacturing sites. The over spray will be collected within the spray booth on protective materials (e.g., kraft paper or newspaper) and any volatile materials will be captured by the filtering system.

The notified polymer, imported as such, will not be available to the general public. However, coatings containing the notified polymer will be available for DIY users and it is expected that up to 50% of the coatings containing the notified polymer will be available for the general public. The application of the coatings available to the general public will be via brush and roller only. The application details concerning brush and roller is expected to be similar for both industrial and public use.

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)*
Transportation and warehouse	10	1	200
Reformulation into coatings:			
Mixing and dispersion	40	4	30
Make up	40	2	30
QC Testing	10	8	30
Filtering and Packaging	40	8	30
Cleaning of equipment	30	2	200
End- use applications	>1000	3	100 to 200

EXPOSURE DETAILS

Transport and storage

During transportation, warehousing, and distribution to coating manufacturing sites of products containing the notified polymer, exposure to the notified polymer is not expected, except in the unlikely event of an accident where the packaging is damaged. Workers are expected to wear gloves and safety goggles to minimise any exposure when handling the notified polymer as introduced.

Manufacture of coatings

There is potential for dermal, ocular and inhalation exposure to the notified polymer (<40%) during its reformulation into coating products. However, exposure is expected to limited due to the use of: a pump to transfer the product containing the notified polymer at <40% concentration to the mixing vessel, a closed mixing vessel for mixing notified polymer with other ingredients, mechanical agitators under local exhaust ventilation for blending, automated and enclosed transfer and packaging processes, and personal protective equipment (PPE) such as gloves, overalls, eyewear. There may be some exposure as a result of drips and spills during the connection and disconnection of transfer pipes, but exposure will be minimised by the use of PPE as stated above.

End-use application of coatings

Dermal, ocular and inhalation exposure to the notified polymer (at <30%) may occur during mixing and transfer of the coating to spraying equipment, during application and also during equipment cleaning and maintenance. However, exposure during spray application will be minimised by the use of ventilated spray booths at industrial manufacturing facilities. In addition, workers will wear, as a minimum, eye protection, overalls, impermeable gloves and, if necessary, a respirator.

Dermal and ocular exposure to the notified polymer (<30%) may also occur during brush and roller applications, particularly during manual mixing, manual decanting and manual application. Dermal and ocular exposure is expected to be minimised by the use of PPE such as overalls, safety glasses and gloves. In addition, the finished coating is expected to be touch-dry within two hours after application, minimising the potential exposure duration. Application equipment, such as rollers and brushes, will be cleaned with industrial solvents (such as mineral spirits), and washings will be held in storage tanks prior to disposal by licensed waste contractors. It is expected that workers will use, as minimum, PPE such as gloves, overalls, and goggles for this purpose.

Maintenance and cleaning of equipment

Dermal, ocular and inhalation exposure to the notified polymer at <40% concentration may occur during maintenance and cleaning of equipment used in manufacturing of coating. Maintenance and cleaning of equipment will occur on a regular basis. Workers will wear gloves, safety glasses, apron, and respirator (if required) in order to minimise any possible exposure.

Overall, based on the use of engineering controls and PPE by workers, exposure during various procedures/processes involving the use of notified polymer is expected to be low.

6.1.2. Public exposure

The application of the coatings by the general public will only be via brush and roller methods. Although it is expected that the nature and type of exposure to DIY users will be similar to that of commercial/industrial users, the frequency of exposure will be less than that of commercial/industrial users. The use of gloves and body-covering clothing is recommended for DIY users during the application of coatings containing the notified polymer. Once cured, the notified polymer is expected to be bound within an inert matrix and is not expected to be bioavailable.

Members of the general public may also experience dermal exposure to surfaces coated with the notified polymer at <30% concentration. The notified polymer in this case is expected to be bound within an inert matrix and is not expected to be bioavailable. Therefore, public exposure to the notified polymer is expected to be low. Therefore, based on the above, public exposure to the notified polymer is expected to be low.

6.2. Human health effects assessment

As no toxicity data were submitted, it is not possible to establish the hazard potential of the notified polymer.

Based on the high molecular weight (> 10,000 Da) and negligible proportion of low molecular weight species (< 1,000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. As such, systemic toxicity following dermal exposure to the notified polymer is expected to be low.

The notified polymer contains functional groups that may be considered to be structural alerts for skin sensitisation and corrosion/irritation. Although the potential sensitisation or corrosion/irritation effects cannot be ruled out, these risks are not considered significant, given the high molecular weight of the notified polymer, the negligible proportion of low molecular weight species, and the concentration of the notified polymer (<30%) in paint and coatings.

Health hazard classification
In the absence of toxicity data, the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary risk to workers from exposure to the notified polymer is the potential for sensitisation and/or corrosion/irritation effects.

There is a risk for potential occupational exposure (dermal, ocular and inhalation) to the notified polymer (<40% and <30%) during various manufacturing and coating application processes. However, exposure is expected to be limited due to the use of engineering controls (enclosed systems, automated procedures, local exhaust ventilation) and PPE (gloves, overalls, safety glasses) expected to be worn when handling the notified polymer. In addition, the finished coating is expected to be touch-dry within two hours after application, minimising the potential risk for any further exposure after application.

There is an additional risk of occupational exposure to the notified polymer during application by spraying equipment. However, exposure is expected to be limited due to the use of ventilated spray booths at industrial manufacturing facilities and the use of PPE (gloves, overalls, safety glasses). In addition, a respirator will also be worn by workers if required to control inhalation exposure. Similarly, the use of PPE such as gloves, safety glasses, apron, and respirator (if required) will also minimise any potential for occupational exposure during maintenance and cleaning of equipments.

Overall, based on the use of engineering controls, safe work practices and PPE, the risk to workers from using the product containing the notified polymer is not considered to be unreasonable.

6.3.2. Public health
There is risk for DIY users to be exposed to the notified polymer during preparation and application of coatings containing the notified polymer (<30%). The application of the coatings available to the general public will only be via brush and roller methods.

Although it is expected that the exposure to DIY users will be similar to that of commercial/industrial users, for the brush and roller application scenarios, the frequency of exposure will be less than that of commercial/industrial users. The recommended use of gloves and body-covering for DIY users during the application of products containing the notified polymer will limit the potential for exposure. Once cured, the notified polymer is expected to be bound within an inert matrix and is not expected to be bioavailable, thereby limiting any further potential for exposure.

Therefore, the overall risk posed by the use of products containing the notified polymer by brush or roller is not considered to be unreasonable to the health of the public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be blended with other chemicals into finished coating and paint products in Australia. The notified polymer is unlikely to be released to the environment in significant quantities from these reformulation processes except from accidental spills. Spilt polymer (up to 1% of the total imported quantity) is expected to be absorbed in inert material and collected for disposal by a licensed waste contractor. Small amounts of the annual import volume of the notified polymer (< 1% the total imported quantity) will be present in washings arising from equipment cleaning, and are expected to be flocculated and disposed of to landfill. Drums containing notified polymer residues are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The coatings and paint products containing the notified polymer are expected to be used by both professionals and do-it-yourself (DIY) practitioners, with each group expected to utilise approximately half of the total import volume of polymer. All users are expected to apply coatings with brushes and rollers, while spray applications are only anticipated in industrial settings. During spray applications, overspray will be captured in spray booths and on kraft paper or newspaper. The product is expected to be dried on to the paper and disposed of to landfill. At industrial sites, application equipment will be cleaned with an appropriate cleaning solvent and washings will be held in storage tanks prior to disposal. Of the 50% of paint containing the notified polymer used by DIY practitioners, it is estimated that 5% of the paint will be released to sewers due to the washing of brushes and rollers with water. Under this scenario, 2.5% of the total import volume of notified polymer (5% × 50%) is assumed to be released to sewer annually.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to share the fate of the substrates to which the paint containing the polymer has been applied, and hence will be disposed to landfill. A small proportion of the notified polymer is expected to enter landfill in the form of dried paint residues in used paint containers.

7.1.2 Environmental fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight much greater than 10,000 Da and no significant percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes and therefore will not bioaccumulate.

The notified polymer is expected to be efficiently removed from waste water in waste water treatment plants through adsorption of this ionic polymer to sludge or by flocculation (Boethling and Nabholz, 1997). The notified polymer is therefore expected to be concentrated in the sludge fraction of on-site or municipal waste water treatment plants. Sludge generated during the treatment process will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil and sludge due to its ionic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). Cured notified polymer is anticipated to be bound within an inert matrix and is not expected to be bioavailable nor mobile. The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon, nitrogen and sulfur.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC was calculated assuming that 2.5% of the total import volume of polymer would be released nationwide to sewer annually, from DIY use. It was further assumed that 90% of the notified polymer partitions to sludge in STPs due to its potential positive charge (Boethling and Nabholz, 1997). The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	200,000	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.70	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.32	µg/L
PEC - Ocean:	0.03	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 29 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.194 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 0.97 mg/kg and 1.94 mg/kg, respectively.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by a mitigation factor to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 66 mg/L	Harmful
Daphnia Toxicity	EC50 (48 h) > 100 mg/L	Not Harmful
Algal Toxicity	EC50 (96 h) = 36 mg/L	Harmful

The notified polymer is potentially harmful to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for algae. The endpoint for algae was therefore selected for the calculation of the PNEC below. A conservative assessment factor of 1000 was applied since ecotoxicity endpoints were calculated using SAR equations based on groupings of broadly related polymers.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae (EC50, 96 h)	36	mg/L
Assessment Factor	1000	
PNEC:	36	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.32	36	9×10^{-3}
Q - Ocean	0.03	36	9×10^{-4}

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be << 1 based on the above calculated PEC and PNEC. The Q value indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its assessed use pattern at the proposed maximum import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
In the absence of toxicity data, the notified polymer cannot be classified as hazardous according to 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 PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced and as diluted for use:
  - Local Exhaust ventilation
  - Enclosed and automated systems

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and as diluted for use:
  - Avoid contact with eyes and skin.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and as diluted for use:
  - Chemical resistant gloves
  - Overalls
  - Safety glasses

  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 *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.

- 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.

Public Health

- Products marketed to the public containing the notified polymer should not recommend application by spraying.

Disposal

- The notified polymer should be disposed of to landfill.

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(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;
- additional information becomes available as to the sensitisation or corrosion/irritation potential of the notified polymer.

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from as a component of coatings and paint (<30%) for both industrial and DIY uses, or is likely to change significantly;
- the amount of polymer being introduced has increased from 200 tonnes/annum, 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 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.

BIBLIOGRAPHY

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