File No: LTD/1610

July 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in NeoCryl XK-89

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 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800	
FAX: + 61 2 8577 8888	
Website:	www.nicnas.gov.au

Director
NICNAS

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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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1610	Reschem Technologies Pty Ltd	Polymer in NeoCryl XK-89	ND*	300 tonnes per annum	A component of paints and lacquers

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer cannot be classified as hazardous under the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(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

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - 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.
  - Avoid inhalation of aerosols during spray application

- 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
  - Respiratory protection if aerosols are generated

  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 Da.

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from as a component of paints and lacquers or is likely to change significantly;
  - the amount of polymer being introduced has increased from 300 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 a 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Reschem Technologies Pty Ltd (ABN 90 315 656 219)
Suite 1103/4 Daydream St Warriewood NSW 2102

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, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physicochemical properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NeoCryl XK-89 (containing the notified polymer at < 45%)

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is stable under normal conditions of use and storage. No loss of monomers or other reactants is expected.

DEGRADATION PRODUCTS
The notified polymer is stable under the normal conditions of use and storage. Degradation products on heating to > 250 º C are expected to be oxides of carbon, nitrogen and sulfur.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: milky white liquid (product containing the notified polymer)

Property	Value	Data Source/Justification
Melting Point	Not determined	-
Boiling Point	Not determined	Imported in liquid formulation
Density	1040 kg/m^3 at 20 °C*	MSDS
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
Water Solubility	Water dispersible at pH 7*	Analogue data
Hydrolysis as a Function of pH	Not determined	Contains functional groups that are expected to hydrolyse very slowly in the environmental pH range (4-9).
Partition Coefficient (n-octanol/water)	Not determined	Expected to have a low partition coefficient on the basis of the water

		dispersibility and the low solubility in octanol of an analogue.
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge based on its high molecular weight and presence of potentially cationic functionality.
Dissociation Constant	Not determined	Contains dissociable functional groups (estimated pKa ~ 4.7, 8.9). Expected to be ionised in the environmental pH range (4-9).
Particle Size	Not determined	The notified polymer is supplied in liquid formulation and is not isolated from this formulation during its life cycle in Australia.
Flash Point	Not determined	Not isolated from formulation.
Autoignition Temperature	Not determined	Not isolated from formulation.
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

*For imported product containing the notified polymer at < 45%.

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

Reactivity
The notified polymer is not expected to be reactive under the normal conditions of use and handling.
Dangerous Goods classification
Based on the limited submitted physical-chemical data in the above table the notified polymer is not classified 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 is not manufactured in Australia and it will be imported in formulation at < 45% in 120 kg or 1012 kg Intermediate bulk containers (IBCs).

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
Sydney, Melbourne, Brisbane and Perth

TRANSPORTATION AND PACKAGING
The notified polymer will be transported by road or rail to the notifier's warehouse in sealed 120 kg or 1012 kg IBCs. Repackaging will not occur at the notifier's site. The imported formulation will be transported by road and rail to several sites around Australia where it will be formulated into coatings. The final coatings containing the notified polymer at up to 35% will be transported in smaller containers by road to end users and retailers.

USE
The notified polymer will be used as a component (at up to 35%) in paints and lacquers.

OPERATION DESCRIPTION

Coating Formulation

The mixture containing the notified polymer (at < 45%) will typically be pumped into a closed mixing vessel, to which other coating components are added. The mixture in the mixing vessel will be blended using mechanical agitators under local exhaust ventilation. Following dispersion, the coating (containing the notified polymer at up to 35%) will be pumped through automated filling lines for repackaging. Transfer and packaging processes are enclosed.

End Use

Coatings containing the notified polymer (up to 35%) will be applied to substrates such as metal, wood and masonry by spray, roller and brush. Spray application will be conducted in spray booths located in industrial sites.

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)*
Transport and storage	6	240
Paint formulation process operator	6	240
Quality control	0.5	240
Packaging	2	240
End use	6	240

EXPOSURE DETAILS

Transport and storage workers may come into contact with the imported product containing the notified polymer (at < 45%), only in the unlikely event of an accident.

During paint formulation processes, including transfer, quality control and cleaning and maintenance tasks, dermal and ocular exposure to the notified polymer may occur and inhalation may occur if aerosols are generated. Exposure is expected to be minimised through the use of local exhaust ventilation and the use of personal protective equipment (PPE), including chemical goggles, impervious gloves and appropriate industrial clothing.

At end-use sites, dermal, ocular and/or inhalation exposure to the coatings containing the notified polymer (at up to 35% concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the use of safe work practices and PPE by workers (goggles, impervious gloves, appropriate clothing and respiratory protection during spray application). Exposure during spray application will be minimised by the use of spray booths. Once cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public Exposure

Finished coatings containing the notified polymer at up to 35% concentration will be available for use by the general public and may compose up to 80% of the total import volume. Dermal and ocular exposure of the public to the notified polymer may occur during painting applications using brush and roller, particularly during the manual decanting and the manual applications, and cleaning of equipment. Exposure will be minimised if personal protective equipment is worn. Spray application by the public is not expected. The notifier indicated that spray application will be conducted in spray booths located in industrial sites.The general public may come in contact with articles coated with paints containing the notified polymer; however the notified polymer will be cured into the inert matrix and will not be bioavailable.

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), the potential of the notified polymer to be dermally absorbed after exposure is limited. The notified polymer contains functional groups that may be considered to be structural alerts for corrosion/irritation. However the potential will be reduced by the high molecular weight of the notified polymer and the negligible proportion of low molecular weight species.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified 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 highest risk to workers is likely to occur at end-use sites, where the coating component containing the notified polymer is applied by brush, roller or spray. At these sites, PPE is available to reduce exposure, and spray application is carried out in spray booths.

The imported products containing the notified polymer are classified as hazardous, and the precautions against exposure to the products may reduce exposure and risk from the notified polymer. After application and once dried, the notified polymer will be trapped in an inert polymer matrix and will not be bioavailable.

Overall, the risk to workers during blending and application of coatings containing the notified polymer at up to 35% concentration is not expected to be unreasonable given the appropriate use of workplace controls to minimise exposure.

6.3.2. Public Health
DIY users may have dermal/ocular exposure to the notified polymer during use of coatings containing the notified polymer (up to 35%). 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. Use of PPE would limit the potential for exposure and any irritation effects. 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 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 with 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 coating products containing the notified polymer are expected to be used by both professionals and do-it-yourself (DIY) users. DIY use is expected to account for 80% of the total import volume. 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 onto the paper and disposed of to landfill. Less than 1% of the notified polymer may remain as residues in the product containers which are expected to be disposed of to landfill. Equipment used to apply the formulations may be rinsed with water. An estimated 1% of the annual importation volume of notified polymer used in coatings may be released to sewers due to application equipment rinsing in industrial settings. For DIY use, it is estimated that up to 5% of the import volume of notified polymer may be released to sewers in wash water from rinsing application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

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

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer.

The majority of the notified polymer is expected to be disposed of to landfill as an inert polymeric matrix of cured coatings adhering to articles. In this form, the notified polymer is not expected to be mobile, bioavailable nor bioaccumulative.

Some of the notified polymer may be released to sewers in waste water from application equipment rinsing. 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). Sludge generated during the treatment process may be sent to landfill for disposal or agricultural land for soil remediation. The notified polymer is expected to adsorb to soil and sludge due to its high molecular weight and ionic functions. Therefore, it is not expected to be mobile in the environment.

Since the notified polymer has a molecular weight 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 is not likely to bioaccumulate. An analogue containing similar functionality as the notified polymer, but of higher molecular weight, was reported to be not readily biodegradable (3.2% BOD in a 28-day study; full study report not available). Therefore, the notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) was calculated assuming that 5% of the total annual import volume of notified polymer would be released nationwide to sewer from DIY use. It was further assumed that 90% of the notified polymer partitions to sludge in sewage treatment plants (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	300,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	15,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	41.10	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.91	µg/L
PEC - Ocean:	0.09	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 81.8 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 polymer may approximate 0.545 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 2.73 mg/kg and 5.45 mg/kg, respectively.

7.2. Environmental Effects Assessment

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

Endpoint	Result	Assessment Conclusion
Fish Toxicity	LC50 (96 h) = 9.6 mg/L	Toxic
Daphnia Toxicity	EC50 (48 h) > 100 mg/L	Not Harmful
Algal Toxicity	EC50 (96 h) = 12 mg/L	Harmful

The notified polymer is potentially toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. 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. 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 predicted no-effect concentration (PNEC) has been calculated from the estimated acute fish toxicity of the notified polymer and an assessment factor of 500. As aquatic acute toxicity endpoint estimates were available for one species in each of the three trophic levels an assessment factor of 100 to 1000 is appropriate to account for extrapolation of acute to chronic effects and from laboratory to field conditions. A conservative assessment factor of 500 was used given the endpoints were calculated using SAR equations.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	9.60	mg/L
Assessment Factor	500	
PNEC:	19.2	µg/

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Q) have been calculated for the aquatic compartment.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.91	19.2	0.047
Q - Ocean:	0.09	19.2	0.005

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations. The assessment of environmental risks is based on the notified polymer's reported use pattern, annual introduction volume and its partial removal from waste water by sorption to sewage sludge. The notified polymer is expected to be persistent in the environment but is considered to have low potential for bioaccumulation. Therefore, on the basis of the PEC/PNEC ratio and assessed use pattern the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Water dispersible at pH 7

Method In house

Remarks Solubility in water and octanol was determined for an aqueous product containing an analogue polymer and surfactant (corrected for polymer content). The full test report was not provided. The results are summarised below.

Water solubility was determined for samples of the analogue at pH 7 that were centrifuged at 9,000 rpm and 17,000 rpm following equilibrium. Water solubility for the analogue was reported to be 1750 mg/L and 452 mg/L, respectively. The results stated that water solubility could not be determined at pH 1 and 10.

Octanol solubility was reported to be < 22.1 mg/L.

The analogue polymer contains similar functionality with similar ratios to the notified polymer but was of higher molecular weight. The solubility results for the analogue are considered suitable to provide indicative solubility of the notified polymer based on structural considerations. While the presence of surfactant may affect the solubility of the analogue polymer, neither the analogue nor notified polymer is ever isolated from product containing the surfactant. Therefore, the results of the test are considered suitable to provide indicative solubility for the notified polymer in the imported product.

The analogue polymer solubility results support expert judgement that the notified polymer is expected to be water dispersible based on the presence of hydrophilic functionality and its use in aqueous products.

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