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June 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in NeoCryl XK-14

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:

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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1808	Reschem Technologies Pty Ltd	Polymer in NeoCryl XK-14	ND*	≤ 500 tonnes per annum	Component of coatings, adhesives and 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
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 safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid skin contact

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System 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 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 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 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;
- the notified polymer is intended for use in packaging for food and/or beverage products

or

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

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

(Material) Safety Data Sheet
The (M)SDS of the product containing 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 (ABN: 90 315 656 219)
Suite 1103/4 Daydream Street
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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada and China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NeoCryl XK-14 (contains the notified polymer at < 20% concentration in aqueous solution)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow translucent liquid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Solid at ambient temperature
Boiling Point	Not determined	Expected to decompose without boiling
Density	1,050 kg/m^3 at 20 °C	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	Not determined	Expected to be water dispersible based on the presence of hydrophilic functionalities and its use in aqueous products
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups that are expected to hydrolyse slowly in the environmental pH range (4 – 9) at ambient temperature
Partition Coefficient	Not determined	Expected to have a low partition

Property	Value	Data Source/Justification
(n-octanol/water)		coefficient on the basis of its water dispersibility
Adsorption/Desorption	Not determined	Expected to partially adsorb to soil, sediment and sludge based on its high molecular weight
Dissociation Constant	Not determined	The notified polymer contains ionisable functionalities and expected to be ionised in the environmental pH range (4 – 9)
Flash Point	Not determined	Introduced in aqueous solution
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not determined	Not expected to be explosive based on structure
Oxidising Properties	Not determined	Not expected to be oxidising based on structure

* For the imported product Neocryl XK14 containing the notified polymer at < 20% concentration in aqueous solution.

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal 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 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 at < 20% concentration in aqueous solution for formulation of coatings, inks and adhesives. The imported product may also be used as a finished coating product without further reformulation.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 100	< 500	< 500	< 500	< 500

PORT OF ENTRY
Adelaide, Brisbane, Melbourne, Perth and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer at < 20% concentration in aqueous solution will be imported in 120 kg plastic drums or 1,050 kg IBCs. The finished products (coatings, inks and adhesives) containing the notified polymer at < 20% concentration will be packaged in 250 mL to 1000 L containers for industrial users and 250 mL to 25 L containers for DIY users.

USE
The notified polymer will be used as a component of coatings, inks and adhesives at < 20% concentration. The finished coating products may be used by DIY users.

Ink applications include use in industrial graphics, flexible packaging, film coatings, can coatings, paper and board packaging. Adhesive applications include plastic and glass bottle labels, industrial, film and wood lamination, underbody automotive applications, flexible packing and heat seal lacquers.

OPERATION DESCRIPTION
The imported product containing the notified polymer will be used in the formulation of coatings, inks and adhesives. The imported product may also be used as a finished coating product without further reformulation.

Reformulation
At the reformulation site, the product containing the notified polymer (at < 20% concentration) will typically be pumped (using automated or semi-automated processes) into a closed mixing vessel, to which other ingredients will be added. The reformulated product (containing the notified polymer at < 20% concentration) will be filtered and pumped into containers using automated and metered processes. Quality control personnel may sample the final reformulated product containing the notified polymer.

End use
Coatings containing the notified polymer may be applied by brush, roller or spray on a wide range of substrates by both commercial and domestic users.

Inks and adhesives containing the notified polymer will be applied in industrial settings. The application process is expected to be largely enclosed and automated.

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 warehouse	4	20
Reformulation	8	40

EXPOSURE DETAILS
Transport and storage workers may come into contact with the notified polymer (at < 20% concentration) only in the event of accidental rupture of containers.

Reformulation
Reformulation will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified polymer (at < 20% concentration) during transfer processes, quality control testing and cleaning and maintenance. Dermal and ocular exposure to workers should be mitigated through the expected use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected given the expected low vapour pressure of the notified polymer and enclosed processes.

Coating applications
At end-use sites, dermal, ocular and inhalation exposure to coatings containing the notified polymer (at < 20 % concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers, including the use of appropriate respiratory protection during spray application.

Adhesive and printing applications
Dermal or ocular exposure may occur to inks and adhesives containing the notified polymer (at < 20% concentration) during transfer and cleaning processes. Inhalation exposure is not expected given the expected low vapour pressure of the notified polymer. Exposure at other times is expected to be limited by the automated and enclosed nature of the application processes. The expected use of PPE by workers, such as goggles, impervious gloves and coveralls should minimise exposure.

Workers may come into contact with the coatings, inks and adhesives containing the notified polymer after application to substrates. However, once the coatings, inks and adhesives have dried, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The public may be exposed (dermal. ocular or inhalation) to the notified polymer during use of coatings containing the notified polymer at < 20% concentration.

The public may come into contact with the coatings, inks and adhesives containing the notified polymer after application to substrates. However, once the coatings, inks and adhesives have dried, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a high molecular weight (> 1,000 Da) and a low percentage (< 3%) of low molecular weight species < 1000 Da; hence absorption across biological membranes is expected to be limited.

The notified polymer contains a functional group (ketone) which is a structural alert for skin irritation (Hulzebos et al., 2005) and sensitisation (Barratt et al., 1994). However, the potential for causing these effects may be limited by the high molecular weight of the notified polymer and low percentage of low molecular weight species < 1000 Da.

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

The notified polymer has the potential to be a skin irritant and a sensitiser, due to the presence of a relevant structural alert. However, the risk of irritation and sensitisation effects from exposure to the notified polymer may be limited by the high molecular weight (> 1,000 Da) and low percentage (< 3%) of low molecular weight species < 1000 Da.

During reformulation and end use, workers may be exposed to the notified polymer at concentrations of < 20%. Given the relatively low use concentration, high molecular weight and low percentage of low molecular weight species limiting dermal absorption, the potential risk of irritation and sensitisation effects is expected to be low. Once the coatings, inks and adhesives have cured and dried, the notified polymer will be bound within an inert matrix and will not be available for exposure. Therefore, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer has the potential to be a skin irritant and a sensitiser. Exposure to the notified may occur during use of coatings containing the notified polymer at < 20% concentration. Given the low end use concentration, high molecular weight and low percentage of low molecular weight species limiting dermal absorption, the potential risk of irritation and sensitisation effects is expected to be low. Once the coatings have cured and dried, the notified polymer will be bound within an inert matrix and will not be available for exposure. Therefore, the risk to the public from use of the notified polymer 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 to Australia for reformulation into coatings, inks and adhesives. During reformulation, spills and leaks are expected to be collected and disposed of via a licensed waste contractor. Empty containers are likely to be disposed of to landfill. The notified polymer in tank wash-outs is expected to be released to sewer or sent to an external waste treatment company.

At the reformulation site, the product containing the notified polymer (at < 20% concentration) will typically be pumped (using automated or semi-automated processes) into a closed mixing vessel, to which other ingredients will be added. The reformulated product (containing the notified polymer at < 20% concentration) will be filtered and pumped into containers using automated and metered processes. Release of the notified polymer from reformulation process is not expected to be significant.

RELEASE OF CHEMICAL FROM USE
The majority of the release of the notified polymer from use to the environment will be from spills and washings of application equipment which are expected to be released to the sewer. After application the notified polymer will be incorporated within an inert matrix and is not expected to be released.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer in coatings, inks and adhesives is expected to share the fate of the substrate to which it has been applied and is expected to be disposed of to landfill, or be recycled. Up to 50% of the notified polymer used in ink application may be released to sewers as residues in recycling waste waters. Empty containers containing residues of the notified polymer are expected to be disposed of to landfill.

7.1.2. Environmental Fate
No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as waste from residues in empty import containers, and articles at the end of their useful life.

Coatings and adhesives
No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as an inert polymeric matrix of cured coatings and adhesive adhering to articles. In this form, the notified polymer is not expected to be mobile, bioavailable nor bioaccumulative. The uncured notified polymer is not expected to be readily biodegradable. However, bioaccumulation is not expected due to its high molecular weight. In landfill and the aquatic compartment, the notified polymer is expected to eventually degrade biotically and abiotically to form water, oxides of carbon and nitrogen.

Ink
Approximately half of the paper to which the ink containing the notified polymer is applied is likely to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified polymer is anticipated to partition to sludge and/or sediment based on its low water solubility and anionicity. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The majority of the notified polymer in sludge 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 and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
It was indicated by the notifier that the notified polymer will be used as a component of coatings, inks and adhesives. It was conservatively assumed that 100% of the total import volume of the notified polymer will be used as ink for printing on papers. Of this, it is assumed that 50% of the total import volume of notified polymer may be released to sewer from recycling processes. A Predicted Environmental Concentration (PEC) for the worst case scenario has been calculated on the assumptions the recycling processes occurs only on working days, which is 260 days per annum. In STPs the notified polymer, which is an anionic polymer, is expected to be approximately 50% removed from influent by adsorption to sludge or by flocculation (Boethling and Nabholz, 1997). Since a PEC value is calculated for a release scenario for ink, which is the worst case release scenario of the three proposed uses, PECs for use in coating has not been calculated.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	250,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	961.54	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	50%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	106.31	µg/L
PEC - Ocean:	10.63	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 106.305 µg/L may potentially result in a soil concentration of approximately 708.7 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 3.54 mg/kg and 7.08 mg/kg, respectively.

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 1063.052 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 7.087 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 35.435 mg/kg and 70.87 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Anionic polymers are generally of low concern to fish and aquatic invertebrates (L(E)C50 > 100 mg/L), but can be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. The EC50 for algae of the most toxic anionic polymers is 3 mg/L. This does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae. Based on the polymer structure of the notified polymer (distance between acids: 2 carbons), the ecotoxicity of the notified polymer to algae is expected to be 150 mg/L (Boethling & Nabholz, 1997). The expected ecotoxicity data of the notified polymer is considered not harmful to algae, and in general, anionic polymers exhibit low toxicity to fish and aquatic invertebrates.

The estimation procedure used here is based on data for similar polymers and is considered acceptable for the purpose of risk assessment. However, this toxicity estimation 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) was calculated using the toxicity endpoint for the most sensitive species (Algae) for similar polymers and a conservative assessment factor of 1000. The assessment factor of 1000 was used since the ecotoxicity endpoint for similar polymers was used in lieu of the measured data for the notified polymer.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	150	mg/L
Assessment Factor	1,000	
PNEC:	150	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	106.31	150	0.709
Q - Ocean:	10.63	150	0.071

The risk quotients (Q = PEC/PNEC) for aquatic exposure have been calculated to be < 1. Although the notified polymer has potential to be released into waterways, it is unlikely to pose a risk to the aquatic environment given that it is not expected to be bioaccumulative nor released at ecotoxicologically relevant concentrations. Therefore, 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.

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