File No PLC/1492

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in RHEOLATE® 465

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of the Environment and Energy.

This Public Report is 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

July 2018

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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
PLC/1492	Cintox Australia Pty Ltd	Polymer in RHEOLATE® 465	No	≤ 40 tonnes per annum	Component of coatings and adhesives

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- Water insoluble high molecular weight polymers in the respirable size range (< 10 μm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if aerosol formation is expected.

- If aerosols are formed during the use of the notified polymer, engineering controls and respiratory protection should be used to prevent inhalation exposure.

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

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (Safe Work Australia, 2015) or relevant State or Territory Code of Practice.

- 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 and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

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

Safety Data Sheet

The SDS of a product containing the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2, 38-40 George Street
PARRAMATTA NSW 2150

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, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
RHEOLATE® 465 (product containing the notified polymer at ≤ 35% concentration)

Molecular Weight
Number Average Molecular Weight (Mn) is > 10,000 g/mol.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Milky liquid*
Melting Point/Glass Transition Temperature	Not determined
Density	Not determined
Water Solubility	Not determined. Expected to be < 1 mg/L
Dissociation Constant	Contains anionic functionalities and is likely to be ionised in the environmental pH range of 4-9.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

* Property of RHEOLATE® 465 containing the notified polymer at ≤ 35% concentration

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-20	10-25	10-30	10-35	10-40

Use
The notified polymer will not be manufactured in Australia. It will be imported into Australia either as a component of an aqueous dispersion (at ≤ 35% concentration) for local reformulations into coatings or adhesives or as component of finished coatings (at ≤ 2% concentration) or adhesives (at ≤ 5% concentration). Finished coatings containing the notified polymer will be applied by brush, roller and airless spray and finished adhesives containing the notified polymer will be applied by brush or dispensed directly from a bottle. The finished products will be used primarily by professional workers and to a less extent by do-it-yourself (DIY) users.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

The notified polymer is a high molecular weight (10,000-70,000 g/mol) polymer with low water solubility. Inhalation of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2017). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity, is uncertain.

Occupational Health and Safety Risk Assessment
Workers carrying out spray application of coatings containing the notified polymer at ≤ 2% concentration may experience frequent and/or prolonged inhalation exposure. The risk of lung overloading would be reduced by workplace controls that would reduce exposure such as good ventilation, safe work practices and respiratory protection if inhalation exposure may occur. With the use of these controls, the risk to workers posed by the notified polymer is not considered unreasonable.

Public Health and Safety Risk Assessment
DIY users are not expected to apply coatings containing the notified polymer by spray application. In the event DIY users did use spray application, inhalation exposure to the notified polymer is expected to be short and infrequent. Therefore, given the assumed low hazard, the risk to public health posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted for the notified polymer. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to 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, leading to chelation of essential nutrients (Boethling RS & Nabholz VJ,1997). However, this does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

The notified polymer will not be manufactured in Australia. It will be imported into Australia either in finished coatings/adhesives, or in aqueous dispersions for reformulation into the finished products. The reformulation process will involve transferring the dispersion containing the notified polymer into

a mixer, where it will be blended with other ingredients in a closed system, followed by automatic filling of the finished products into end-use containers. As estimated by the notifier, up to 2% of the import volume of the notified polymer could be released to the environment as residues in empty containers, liquid waste from reformulation equipment cleaning, and accidental spills during reformulation, transport and storage. These releases are expected to be collected and sent to an approved waste management facility for disposal of in accordance with local government regulations.

Finished coatings containing the notified polymer will be applied by brush, roller and airless spray, and finished adhesives containing the notified polymer will be applied by brush or dispensed directly from a bottle. The finished products will be used primarily by professional workers and to a less extent by do-it-yourself (DIY) users. As estimated by the notifier, spraying operations will generally result in 15-20% loss as overspray, which will typically entail disposal of to landfill after being collected and cured. The majority of liquid waste from application equipment cleaning is expected to be correctly disposed of in accordance with local government regulations.

However, based on the notifier's estimation of 16% of the total annual import volume of the notified polymer is used by DIY users, incorrect disposal of liquid waste may occur. Environmental exposure from the worst-case scenario for incorrect disposal has been calculated, as follows. Up to 5% of the amount used by DIY users may be incorrectly disposed of to the sewers, drains, or ground from waste and washing of application equipment. Assuming the releases occur nationwide over the entire year and there is no removal of the notified polymer during wastewater treatment, the predicted environmental concentration (PEC) is estimated to be 0.18 µg/L [(40 tonnes per annum × 0.16 × 0.05) ÷ (24.386 million person × 200 L/day × 365 days per annum). The anionic polymers that are most toxic to algae are known to have EC50 values of > 1 mg/L (Boethling & Nabholz, 1997). As this is likely to be the most sensitive species, an assessment factor of 100 was used to estimate the Predicted No-Effect Concentration (PNEC). Therefore, the estimated PNEC is likely to be > 10 µg/L. Thus, release of the notified polymer from the assessed use pattern is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment.

Following the application, the notified polymer is expected to share the fate of the articles to which it has been applied, either subjected to metal reclamation or being disposed of to landfill at the end of their useful lives. During metal reclamation, the notified polymer will thermally decompose to form water vapour and oxides of carbon, nitrogen and sulfur. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. The notified polymer is not expected to bioaccumulate due to its high molecular weight. The notified polymer in landfill is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulfur.

Therefore, based on its assumed low hazard and the assessed use pattern as a component of coatings and adhesives, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

Safe Work Australia (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-spray-painting-and-powder-coating.

US EPA (2017) High Molecular Weight Polymers in the New Chemicals Program. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new.