File No: LTD/1781

September 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in PUD-001

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:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1781	DIC Australia Pty Ltd	PUD-001	ND*	< 1 tonne per annum	Component of coatings 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
Provided that the recommended controls are being adhered to, under the conditions of the occupational setting, 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 engineering controls to minimise occupational exposure to the notified polymer during use:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation

- 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 during use:
  - Avoid contact with skin and eyes
  - Avoid inhalation

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during use:
  - Respiratory protection, impermeable gloves, googles and coveralls

  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

- 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 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 polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of coatings or inks, 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)
DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2144

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, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
PMN in USA under application

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PUD-001 (aqueous solution containing 30-40% notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference NMR, IR, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be imported and used in an aqueous solution.
Boiling Point	Not determined	The notified polymer will be imported and used in an aqueous solution.
Density	1040 kg/m^3 at 25 °C	(M)SDS*
Vapour Pressure	< 1.3 × 10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	The product containing the notified polymer is miscible in water	(M)SDS*
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environment pH range of

		4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer has a structure characteristic of a surfactant. Therefore, it may partition to the n-octanol/water phase boundary.
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil based on its high molecular weight and presence of ionic functionality which will adsorb to soil and sediment.
Dissociation Constant	Not determined	It is expected to be ionised in the environment given the presence of dissociable functional groups.
Flash Point	Not determined	The notified polymer will be imported and used in an aqueous solution.
Autoignition Temperature	Not determined	The notified polymer will be imported and used in an aqueous solution.
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

* Data for product PUD-001 (aqueous solution containing 30-40% notified polymer)

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to degrade by releasing one of the monomers (N,N-diethylethanamine, CAS No. 121-44-8) during drying, but is otherwise 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 as a component of coatings (up to 40% concentration) or inks (up to 10% concentration).

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

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

PORT OF ENTRY

Adelaide

TRANSPORTATION AND PACKAGING

Coating products containing the notified polymer at up to 40% concentration will be imported in anti-rusting cans or drums and ink products containing the notified polymer at up to 10% concentration will be imported in plastic bottles or sealed cases.

USE

The notified polymer will be used as a component of coatings (at up to 40% concentration) or inks (at up to 10% concentration). Products containing the notified polymer are intended for industrial and professional users only and are not expected to be used by the public.

OPERATION DESCRIPTION

End-use
For coatings, the notified polymer will be imported as an aqueous dispersion at up to 40% concentration and will be blended with other components to form finished coating formulations which will be applied by various coating machinery or by spray.

For printing, the notified polymer will be imported as a component of finished inks at up to 10% concentration which will be used for industrial and professional printing. At a typical printing facility, the ink cartridge will be inserted into the printing machine or a pipe or hose will be connected to the bottles holding the ink formulations and the ink containing the notified polymer will be transferred to the printing machine fitted with exhaust ventilation via an automated and enclosed process.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

Transport and Storage
Transport and storage workers may come into contact with the notified polymer at up to 40% concentration only in the event of an accidental rupture of containers.

End-use
At coating facilities, workers may be exposed (dermal and ocular) to the notified polymer at up to 40% concentration when transferring the product containing the notified polymer from import containers to the mixing tank or transferring finished coatings from the mixing tank to the coating machinery or spray equipment, and during maintenance and cleaning. Exposure should be mitigated by the notifier stated use of personal protective equipment (PPE) including protective gloves and protective goggles. Inhalation exposure is predicted to be limited given the notified polymer's expected low vapour pressure. If coatings containing the notified polymer are applied by spray, inhalation should be minimised by the notifier stated use of local exhaust ventilation and respiratory protection.

Printer operators may be dermally exposed to inks containing the notified polymer at up to 10% concentration during connection and disconnection of lines from containers of ink formulation to the printing machine, during ink filling and during printing maintenance and cleaning. However, exposure is expected to be limited as the processes will be mainly automated and enclosed, and the notifier has stated that workers are expected to use personal protective equipment (PPE). Inhalation exposure may occur if aerosols of the notified polymer are formed during the operation of the printing machinery. However, this is expected to be minimised by local exhaust ventilation employed in areas surrounding printing machines or by use of a respiratory protection in brief use scenarios.

Workers may also be exposed a hazardous chemical (N,N-diethylethanamine, CAS No. 121-44-8) released from the notified polymer during drying in both coating and printing processes. However, exposure is expected to be negligible given the low level of presence of the chemical in the notified polymer, and the use of local exhaust ventilation and PPE.

6.1.2. Public Exposure
Coatings and inks containing the notified polymer at up to 40% concentration are only for use in industrial settings and will not be sold to the public. The public may come into contact with the coatings and inks containing the notified polymer after application to surfaces. However, once the coatings and inks are cured and dried, the notified polymer will be bound to the surface to which it was applied and will not be bioavailable.

6.2. Human Health Effects Assessment
No toxicity data were submitted. The notified polymer is of high molecular weight (NAMW > 1000 Da), highly charged and water soluble hence it is unlikely to be readily absorbed through the skin or gastrointestinal (GI) tract**.** The notified polymer has no structural alerts associated with health hazards.

The primary degradation product is N,N-diethylethanamine (CAS No. 121-44-8) which will be released during drying. N,N-diethylethanamine is classified by Safework Australia to be R35: Causes severe burns (conc.

≥ 25%), R20/21/22: harmful by inhalation/harmful in contact with skin/harmful if swallowed (< 25% conc. ≥ 10%), R34: Causes burns (5% ≤ conc. < 10%) and R36/37/38: irritating to eyes/respiratory system/skin (1% ≤ Conc < 5%).

Health 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).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the high molecular weight and lack of structural alerts of concern the notified polymer itself is not expected to be hazardous to human health. However, the primary degradation product of the notified polymer, N,N-diethylethanamine, is harmful by inhalation, in contact with skin or if swallowed, irritating to eyes, skin and respiratory system, and causes burns.

Industrial and professional workers will be at risk of aforementioned effects from N,N-diethylethanamine when during the use of the imported product containing up to 40% of the notified polymer. However, exposure is expected to be limited by the notifier stated local exhaust ventilation, monitoring of N,N-diethylethanamine's level and use of PPE including respiratory protection, impermeable gloves and googles and coverall. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer will be used in industrial settings only and will not be sold to the public. The public may come into contact with coatings and inks containing the notified polymer after application to surfaces. However, once the coatings and inks are cured and dried, the notified polymer will be bound to the surface to which it was applied and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be blended with other components in Australia to prepare inks and coatings. The blending is expected to be largely automated and will occur in enclosed systems. Waste generated from formulation and cleaning of equipment is expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
Inks containing the notified polymer are expected to be printed on paper. Once printing is complete, the notified polymer is expected to be incorporated in an inert matrix and is not expected to be released from the printed paper. Ink cartridges are designed to prevent leakage and are not expected to be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under normal conditions. Waste inks due to equipment cleaning or spillage is expected to be physically contained with absorbent material and disposed of to landfill.

The coating products containing the notified polymer are expected to be used in industrial facilities. Any losses from overspray (estimated at 30% of annual import volume) during industrial use are expected to be collected using standard engineering controls. These losses, together with other wastes generated during use, including residues in application equipment washings and empty containers, are expected to be disposed of in accordance with local regulations, namely to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Printed waste paper containing the notified polymer is expected to be disposed of to landfill or be subjected to paper recycling. The aqueous wastes from paper recycling are expected to be directed to waste water treatment plants.

Coated articles containing the notified polymer are expected to be thermally decomposed during metal reclamation processes or disposed of to landfill along with the used articles.

Residual ink or paint products left in empty cartridges or empty containers will most likely be disposed of to landfill or be disposed of in compliance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight greater than 1000 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.

Most of the notified polymer is expected to be immobilised within a polymeric film on coated articles after printing and coating applications. The notified polymer will be disposed of along with the used article at the end of its useful life, which, in the majority of cases, will be to landfill. In cases where inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. During paper 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 may partition to the supernatant water, which is expected to be released to the sewer. However, the notified polymer would be expected to be efficiently removed from waste water in waste water treatment plants through adsorption of the ionic polymer to sludge or by flocculation during paper recycling and water treatment processes. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to soil for remediation of agricultural land. The notified polymer is likely to be bound to soil and sludge due to its ionic functions and is not expected to be mobile in the environment. In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is used for ink and coating applications on a variety of substrates, including paper. For the worst case release scenario, it is assumed that 100% of the notified polymer will be used in ink products for paper printing, of which half will be subjected to paper recycling processes. The predicted environmental concentration (PEC) was calculated assuming that the 90% of the notified polymer is removed from influent during sewage treatment processes (STPs) processes by adsorption to sediment and sludge (Boethling & Nabholz, 1997). It was assumed that release of the notified polymer to surface waters occurs from recycling processes over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.43	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 0.0028 mg/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 0.014 mg/kg and 0.028 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. 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 and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity (96 hour)	LC50 = 10.89 mg/L	Harmful
Daphnia Toxicity (48 hour)	EC50 = 248.12 mg/L	Not harmful
Algal Toxicity (96 hour)	EC50 = 16.14 mg/L	Harmful
Chronic Toxicity		
Fish Toxicity	ChV = 0.61 mg/L	Toxic
Daphnia Toxicity	ChV = 13.78 mg/L	Not harmful
Algae Toxicity	ChV = 4.84 mg/L	Not harmful

Based on the worst case SAR estimations, the notified polymer is potentially harmful or toxic 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 for the purposes of risk assessment. 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 fish. The endpoint for fish was therefore selected for the calculation of the PNEC below. An assessment factor of 50 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish (ChV)	0.61	mg/L
Assessment Factor	50	
PNEC:	12.2	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.43	12.2	0.035
Q - Ocean:	0.04	12.2	0.003

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

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