

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

Polyurethane Resin PUD-004

This Self-Assessment has been compiled by the applicant and adopted by NICNAS 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), administered by the Department of Health and the Department of the Environment and Energy, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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:

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**

September 2017

Table of Contents

SUMMARY:	2
CONCLUSIONS AND REGULATORY OBLIGATIONS.....	2
ASSESSMENT DETAILS.....	4
1. APPLICANT AND NOTIFICATION DETAILS.....	4
2. IDENTITY OF POLYMER	4
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	5

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
SAPLC/197	DIC Australia Pty Ltd	Polyurethane Resin PUD-004	No	≤ 2 tonnes per annum	Component of flexographic printing ink

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

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation
Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Service personnel should wear disposable gloves and ensure adequate ventilation is present when cleaning the printing press that uses the ink containing the notified polymer and during routine maintenance and repairs.
- A copy of the 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 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;
 - the notified polymer is intended for use on prints that may come into direct contact with food.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of flexographic printing ink, 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 products containing the notified polymer were 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

Applicants

DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2144

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, and residual monomers/impurities.

2. IDENTITY OF POLYMER

Marketing Name(s)

Polyurethane Resin PUD-004
UD-4001 (aqueous dispersion containing the notified polymer at 35% concentration)

Molecular Formula

Number Average Molecular Weight (Mn) is > 10,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Imported as a water dispersion
Melting Point/Glass Transition Temp	Not determined, imported as a dispersion in water
Density	Not determined
Water Solubility	Expected to be dispersible in water
Dissociation Constant	The notified polymer is a salt and is expected to be dissociate in the environmental pH range (4–9)
Particle Size	Not determined, imported as a dispersion in water
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	1.2	1.4	1.6	1.8	2.0

Use

The notified polymer will be introduced in UD-4001 at 35% concentration in an aqueous dispersion and used as a component of flexographic printing ink.

The notified polymer will not be manufactured in Australia, and will be initially imported in UD-4001 in 200 L steel or plastic drums, and as introduction volume increase, in 1,000 L drums.

Ink manufacturer receiving UD-4001 containing the notified polymer will blend the aqueous dispersion with pigments and additional ingredients to produce ink, and repackage it in 5 L plastic bottles and 18 L plastic pails for distribution. These containers will be sealed, stored in warehouses and then transported by road to end-users (mainly commercial printing establishments).

The ink products containing the notified polymer will not be available to the public and will be used for industrial printing only. The ink products will be printed on to substrates using flexographic and gravure presses machines, and then immediately dried on the substrates by a heating process. The ink containing the notified polymer will be mainly used to print on flexible materials including paper and various films, such as polyester, polypropylene and nylon. These materials will be used for various packages including shopping bags. In the case of food packaging, printed images will be on the outside of the packaging and will not come into direct contact with food contents.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were available. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Although not considered in this risk assessment, the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

Given the assumed low hazard and the assessed use pattern, the risk of the notified polymer to occupational and public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will be imported as a component of a product for reformulation into finished industrial flexographic printing inks. The finished printing inks containing the notified polymer will be applied to packaging paper and film by a flexographic printing unit. Release of the notified polymer to the environment during import, reformulation, storage and transport is expected to be limited to accidental spills or leaks and residue in import containers. Spills or accidental release of the product containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations. Residue in import containers is expected to be minimal. Empty import containers containing residues of the notified polymer will be disposed of through the standard recycling practices for metal and plastic containers of the printing industry.

ENVIRONMENTAL FATE

Most of the notified polymer is expected to share the fate of the paper and film packaging on which it applied to, to be either disposed of to landfill or subject for paper recycling. The notified polymer may also enter landfill as residues in empty import containers. In landfill, the notified polymer presents as cured solid which is neither mobile nor bioavailable. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of inks from the fibres. Very little of the notified polymer is expected to partition to the supernatant water, due

to high molecular weight. Sludge containing the notified polymer is expected to be disposed of in accordance with local regulations. Uncured notified polymer is not expected to cross biological membranes based on its high molecular weight. Therefore, the notified polymer is unlikely to be bioaccumulative. The notified polymer in sludge, soil, and landfill is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.2. Environmental Hazard Characterisation

No eco-toxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they 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. However, this does not apply to the notified polymer, and it is therefore not considered to be an over-chelation hazard to algae.

7.3. Environmental Risk Assessment

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