

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Joncryl® 1335

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**

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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/1386	BASF Australia Ltd	Polymer in Joncryl® 1335	No	≤ 50 tonnes per annum	Component of inks and varnishes

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.

- 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 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;
 - inks or varnishes containing the notified polymer are applied to packaging that is in 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 inks and varnishes 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.

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant

BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

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, and import volume.

2. IDENTITY OF POLYMER

Marketing Name

Joncryl® 1335 (contains the notified polymer at < 40% concentration in aqueous solution)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
Low Charge Density	Not applicable
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	Colourless solid
Melting Point/Glass Transition Temp	140 - 150 °C
Density	1,160 kg/m ³ at 20 °C
Water Solubility	Expected to be water soluble based on the hydrophilic functional groups in the notified polymer
Dissociation Constant	The notified polymer is a salt and expected to be ionised at the environmental pH range (4 - 9)
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	20 - 50	20 - 50	20 - 50	20 - 50	20 - 50

Use

The notified polymer will not be manufactured in Australia. It will be imported into Australia at < 40% concentration for reformulation into inks and overprint varnishes. The final concentration of the notified polymer in end-use inks and varnishes will be < 20%. The ink and varnish containing the notified polymer will be used under industrial settings only and will be applied to paper and plastic packaging films by flexographic printing unit. Some uses will be for the exterior of food packaging, mostly on cardboard boxes. It is possible that indirect food contact may occur.

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.

As some uses of the notified polymer will be for the exterior of food packaging, it is possible that indirect food contact may occur. The public report of this assessment will be forwarded to Food Standards Australia and New Zealand (FSANZ) for their information.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. 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. This is likely to apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions in the aquatic compartment which will bind to the acid functional groups.

The notified polymer will not be manufactured in Australia. However, it will be reformulated in Australia as a component of inks and varnishes for use in paper, plastic and the exterior of food packaging. It is estimated by the notifier that approximate 50 kg/annum of the notified polymer may be released to the environment as a result of spillage and washings for equipment cleaning. Residues of notified polymer in import containers may contribute up to 100 kg/annum of waste. During use, approximately 150 kg/annum of ink waste containing the notified polymer will be generated from equipment cleaning. Residual inks containing the notified polymer in the empty containers (approximately 250 kg/annum) will be rinsed with water. The notifier indicated that aqueous waste will be disposed of through licensed waste disposal contractor after treatment with flocculants and solid waste will be disposed of to landfill.

The ink will be used to print paper, plastic and cardboard boxes. The notified polymer bound within the ink matrix will share the fate of these articles. It is anticipated that the majority of the notified polymer will be disposed of to landfill along with the printed articles and the remainder will be subjected for paper recycling. During the paper recycling process, waste paper will be repulped using a variety of alkaline dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Aqueous wastes containing these agents are expected to be sent to sewage treatment plants (STPs) for processing. The notified polymer is an anionic polymer expected to be water soluble and may not be fully removed by on site wastewater treatment at paper recycling facilities. Some quantities of the notified polymer may therefore be released to surface waters as a result of the de-inking process. Notified polymer partitioned to sludge at STPs is expected to be disposed of to landfill or applied to agricultural soils.

Under the worst case scenario, it is assumed that 50% of the notified polymer will be released to water compartment through STP from paper recycling processes and with no removal of the notified polymer at STPs. The resultant predicted environmental concentration (PEC) of the notified polymer in sewage effluent on a nationwide basis over 260 working days per year is estimated to be 21 µg/L. This PEC is below the EC50 for algae of the most toxic anionic polymers (EC50 > 1 mg/L).

Based on its high molecular weight, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate. In landfill and water, the notified polymer is expected to degrade to water and oxides of carbon and nitrogen.

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