File No.: PLC/1575

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Joncryl 662

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

January 2021

Table of Contents

SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1575	BASF Australia Ltd	Polymer in Joncryl 662	No	< 100 tonnes per annum	Component of industrial printing inks

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Health and Safety Recommendations

- Low pH liquids may cause skin and eye effects. Skin and eye protection should be used when handling the imported product containing the polymer at < 25% concentration.

- Water insoluble high molecular weight polymers used 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 mist/dust/aerosol formation is expected.

  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.

- If products and mixtures containing the assessed 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 assessed polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the assessed polymer is introduced in a chemical form that does not meet the PLC criteria;
- inks containing the assessed polymer are intended to be used on surfaces that may be in direct contact with foods;
- the function or use of the assessed polymer has changed from a component of industrial printing inks, or is likely to change significantly;
- the amount of assessed polymer being introduced has increased, or is likely to increase, significantly;
- the assessed polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the assessed polymer on occupational health and safety, public health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of products containing the assessed 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 APPLICATION DETAILS

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

Protected Information (Section 38 of the Transitional Act)
Data items and details taken to be protected information include: 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 662 (imported product containing the polymer at < 25% 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 assessed polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	White liquid with acrylic-like odour*
Melting Point/Glass Transition Temperature	≈ 0 °C*
Density	1,030 kg/m^3 at 20 °C*
Water Solubility	Not expected to be soluble in water
Dissociation Constant	Expected to dissociate under environmental pH (pH 4-9)
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

* Properties of Joncryl 662 containing the assessed polymer at < 25% concentration.

5. INTRODUCTION AND USE INFORMATION

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

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

Use
The assessed polymer is intended for use in industrial inks in flexographic printers for printing on corrugated board and kraft paper applications.

The assessed polymer will be imported into Australia as a component of Joncryl 662 at a concentration of less than 25%. The imported intermediate product will be transported and stored in either 200 kg closed plastic head drums or 1,000 kg intermediate bulk containers, and will then be reformulated into finished industrial ink products containing the assessed polymer at up to 5% concentration. Finished ink products will be gravity fed through a filter into 20 L or 60 L open head containers and will be transported by road.

6. HUMAN HEALTH RISK ASSESSMENT

The assessed polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by toxicological information for the following endpoints.

Endpoint	*Result*	*Effects Observed*	*Test Guideline*
Skin irritation – *in vitro* RHE EpiDerm	Non-irritating	No	Similar to OECD TG 439
Skin corrosion – *in vitro* RHE EpiDerm	Non-corrosive	No	Similar to OECD TG 431

The imported product containing the assessed polymer is acidic (at approximately pH 2) and therefore may have potential to cause irritation to the skin and eyes. However, the *in vitro* tests provided in the application indicate that the product is not classifiable as an irritant to skin.

Although not considered in this risk assessment, AICIS notes that the assessed 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.

It is noted that the assessed polymer is water-insoluble with molecular weight > 10,000 g/mol. Inhalation of polymers with molecular weights > 70,000 g/mol 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, see https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new, accessed on 16/11/2020). There is a data gap for polymers with MW between 10,000 and 70,000 g/mol, and uncertainty may exist. The assessed polymer is a component of printing ink products. Inhalation of ink particles by workers is possible, however this is expected to only occur at a low level and would be reduced by safe work practices and workplace controls such as good ventilation. If the assessed polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

Given the low hazard, as shown for skin irritation/corrosion endpoints and assumed for other endpoints, the risk of the assessed polymer to occupational and public health is not considered to be unreasonable.

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, leading to chelation of essential nutrients (Boethling & Nabholz, 1997). However, the assessed polymer contains functionalities that dilute the chelating effect, which would result in significantly reduced toxicity to algae.

The assessed polymer will be imported as a component of an aqueous intermediate ink product at < 25% concentration and will be reformulated and repackaged in Australia. The inks containing the assessed polymer will be used in flexographic printers for printing on corrugated board and kraft paper applications. Release may occur due to accidental spills of the ink containing the assessed polymer during import, transport, storage and reformulation and use. These spills, estimated by the applicant to account for up to 0.1% of the import volume of the assessed polymer, are expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations. The applicant estimates that empty containers may contain residues of the assessed polymer up to 0.1% of the import volume which are expected to be sent to landfill for disposal.

Most of the assessed polymer is expected to share the fate of the board and paper to which it has been applied, either subjected to paper recycling processes or being disposed of to landfill at the end of their useful lives. According to the recent Australian National Waste Report (Blue Environment Ltd., 2018), 60% of the wastepaper printed with the assessed polymer is expected to be recycled domestically. During recycling processes, wastepaper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres.

With 60% release of the assessed polymer into the sewer systems through paper recycling processes and no removal within wastewater treatment plants as the worst case scenario, the conservative predicted environmental concentration (PEC) in sewage effluent on a nationwide basis over 260 working days per year is calculated to be 47.3 µg/L [0.6 × 100,000 kg/year ÷ 260 days/year ÷ (24.386 million persons × 200 L/person/day)]. As the assessed polymer is unlikely to be toxic to aquatic organisms, this release of the assessed polymer during the recycling and deinking processes is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment. The assessed polymer is expected to eventually degrade via biotic and abiotic process to form water and oxides of carbon.

The assessed polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

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

BIBLIOGRAPHY

Blue Environment Pty Ltd (2018) Australian National Waste Report 2018. Canberra, Australia.

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.