

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

### POLYMER OF LOW CONCERN PUBLIC REPORT

#### Polymer in Ecovio products

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health and Ageing, 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 Sustainability, Environment, Water, Population and Communities.

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 SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1132	BASF Australia Ltd	Polymer in Ecovio products	No	≤1000 tonnes per annum	Component of food packaging and other plastic products

## 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 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.
- 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 dust is formed during plastic processing.
- 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 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 food packaging and other plastic products, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
  - the method of manufacture of the notified polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the notified polymer on occupational health and safety, public health, or the environment;
  - 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 notified polymer and products containing the notified polymer were 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 Freshwater Place  
Southbank, VIC 3006

##### **Exempt Information (Section 75 of the Act)**

Data items and details claimed exempt from publication: chemical name, CAS number, other names, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and manufacture/import volume.

#### **2. IDENTITY OF POLYMER**

##### **Marketing Name(s)**

Ecovio FS Paper C1500, Ecovio FS Shrink Film C2100, Ecovio IS Injection C1335 EXP, Ecovio FS Film C2332 (notified polymer up to 80% concentration)

##### **Molecular Weight**

Number Average Molecular Weight (Mn) >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	Granules/pellets
Melting Point/Glass Transition Temp	74-136 °C
Density	1169 kg/m <sup>3</sup> at 20 °C
Water Extractability	≤ 0.4% at 20 °C, demineralised water, ≤ 0.4% at 20 °C, pH 2, ≤ 0.6% at 37 °C, pH 7, ≤ 0.5% at 20 °C, pH 9 (OECD 120)
Dissociation Constant	Not determined. The notified polymer contains potential anionic functionalities which are expected to be ionised in the environmental pH range (4 - 9). However, significant ionisation is not expected due to its limited water extractability.
Particle Size	Not determined. Not expected to generate dust
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	100-1000	100-1000	100-1000	100-1000	100-1000

#### Use

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia at a concentration of up to 80%. Products containing the notified polymer will not be reformulated in Australia. The notified polymer will be used for food packaging applications (direct food contact), shrink film manufacture and injection moulding applications at up to 80% concentration.

### 6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 >2000 mg/kg bw	no	OECD TG 423
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

### Occupational Health and Safety Risk Assessment

Given that the notified polymer is of high molecular weight and is insoluble, some concern exists for lung overloading following the inhalation of particles containing the notified polymer. The notified polymer is not expected to generate dust and significant quantities of respirable particles (<10 µm) are therefore not expected.

The risk of the notified polymer to occupational health and safety is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

### Public Health and Safety Risk Assessment

The main route of public exposure may occur from residues from the consumption of food contained in packaging containing the notified polymer. Significant quantities of the notified polymer or residual monomers/impurities are not expected to migrate into food. The notifier has indicated that the notified polymer has been approved for food contact use in the USA.

Given the assumed low hazard, the risk from public exposure to the notified polymer is not considered unreasonable.

## 7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard. This is supported by algal toxicity endpoint observed in a test as summarised in the table below. The test was conducted on the notified polymer in a water accommodation fraction (WAF) solution as the notified polymer is poorly soluble in water.

<i>Endpoint</i>	<i>Result*</i>	<i>Assessment Conclusion</i>	<i>Test Guideline</i>
Algal Toxicity ( <i>Desmodesmus subspicatus</i> )	ErL50 (72 h) > 100 mg/L WAF NOErL ≥ 100 mg/L WAF	Not harmful to algae	OECD

\*The results reported here are based on a nominal loading rate as the actual concentrations of the test substance in the test solutions were not determined.

In this case, as only one acute endpoint for algae is available, an assessment factor of 1000 is considered to be suitable for the calculation of the Predicted No Effect Concentration (PNEC). The PNEC is calculated to be > 100 µg/L (>100 mg/L ÷ 1000).

The notified polymer will be imported into Australia as a component of plastic granules or pellets. The granules or pellets containing the notified polymer will be extruded or moulded locally to manufacture food packaging, shrink wrap film and used for injection moulding applications. During these manufacturing processes, waste from the cleaning of the equipment will be re-pelletised and re-used. Approximately 3% of the notified polymer is estimated to be lost from the trimming of excess moulded material and the resulted waste is expected to be disposed of to landfill. Scraps from the extrusion process (up to 10%) are expected to be collected and recycled, or disposed of to landfill. A negligible amount of notified polymer is expected to remain in the import packaging as the polymer is in pellet form.

The majority of the notified polymer (60% of the total annual import volume) will be physically bound within the inert matrix of the extruded plastic articles which are expected to ultimately be disposed of to landfill. Notified polymer used in food packaging (40%) is expected to be disposed of to landfill as component of used paper products or subjected to paper recycling processes. Assuming that 50% of used paper will be recycled, up to 20% (= 40% × 50%) of the total import volume of

notified polymer is estimated to be released to the aquatic environment due to the recycling of paper products.

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 municipal sewage treatment plants (STPs) for processing. It is assumed that 20% of the notified polymer will be washed into sewers due to paper recycling over 260 days per annum into the total Australian effluent volume. This corresponds to release from recycling processes only on working days. Assuming 90% of the notified polymer will be removed via adsorption to sludge in sewage treatment plants based on its limited water solubility and high molecular weight (Boethling & Nabholz, 1997), the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 17.01 µg/L [ $\text{PEC}_{\text{river}} = 769.23 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 22.613 \text{ million people}) \times 10\%$  (due to 90% removal in STPs)]. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to agricultural soils. The calculated PEC is much less than the PNEC estimated for the notified polymer. Therefore, the notified polymer is not expected to be present in the environment at ecotoxicologically significant levels.

In landfill, the notified polymer is not expected to be bioavailable or mobile due to its low water extractability and high molecular weight. The notified polymer is not expected to be readily biodegradable but due to its high molecular weight it is not expected to bioaccumulate. It is expected to eventually degrade by biotic and abiotic processes in landfill to form water and oxides of carbon.

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

#### **BIBLIOGRAPHY**

Boethling RS & Nabholz JV (1996) 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. New York, Van Nostrand Reinhold, pp 187–234.