

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

### POLYMER OF LOW CONCERN PUBLIC REPORT

#### BioPBS (FZ type) Polymer

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**

July 2017

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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/1409	Chemiplas Australia Pty Ltd	BioPBS (FZ type) Polymer	No	≤ 100 tonnes per annum	Polymer in plastic moulding.

## 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**

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer in powder form :
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m<sup>3</sup>.
  - If the polymer is introduced as a powder in the respirable size range (< 10 µm), respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure.

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 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.or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from use in plastic moulding, 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 the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

## ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified polymer by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on the safe use of the notified polymer were carried out by NICNAS.

### 1. APPLICANT AND NOTIFICATION DETAILS

#### Applicants

Chemiplas Australia Pty Ltd (ABN: 29 003 056 808)  
Level 1, 128 Jolimont Road  
EAST MELBOURNE VIC 3002

#### 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, spectral data, purity, polymer constituents, residual monomers/impurities, use details and import volume.

### 2. IDENTITY OF POLYMER

#### Marketing Name(s)

BioPBS (FZ type) Polymer

#### Other Name

GS Pla FZ type Polymer

#### Molecular Weight

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	White solid.
Melting Point/Glass Transition Temp	90-120°C
Density	1200-1300 kg/m <sup>3</sup>
Water Solubility	The polymer is expected to have low solubility in water based on its high molecular weight and the predominantly hydrophobic structure
Particle Size	1-5 mm (pellet). The polymer may also be imported in powder form.
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	1-10	10-30	10-30	30-60	50-100

### Use

The notified polymer will be imported in pellet or powder form and used in thermal plastic moulding of articles including fibres and film. It may be used for food contact applications. The notified polymer will be present in the final products at a concentration of up to 100%.

## 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: In an acute oral toxicity study in rats according to OECD TG 423, the LD<sub>50</sub> was 2000 - 5000 mg/kg. The notified polymer was not mutagenic in a bacterial reverse mutation test according to OECD TG 471.

The notified polymer is a high molecular weight (10,000-70,000 Da) polymer with expected low water solubility. Inhalation of respirable particles of polymers with molecular weights > 70,000 Da 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, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>), accessed on 26 May 2017). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer, if it is imported in powder and has a respirable particle size (< 10 µm). If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity of the effect(s), are uncertain.

### Occupational Health and Safety Risk Assessment

The notified polymer will be imported in pellet form, however is also available in powder form. Dermal and ocular exposure to pellets/powder containing the notified polymer may potentially occur during certain processes involving the notified polymer, such as when blending and transferring before moulding and cleaning. Inhalation exposure may also occur, particularly if the polymer is in powder form. Worker exposure will be limited because of the largely automated processes, the engineering controls, and personal protective equipment worn by workers (gloves and safety goggles).

If the notified polymer is imported in powder form, and has a respirable particle size, there is a risk of lung overloading from inhalation of the powder. However inhalation is expected to be minimised by the worker controls in place. Once cured/moulded, the notified polymer is encapsulated within the polymer matrix and not expected to be available for exposure.

Based on the occupational scenarios and the proposed controls, the risk to workers is not considered to be unreasonable.

### Public Health and Safety Risk Assessment

Members of the public may make contact with plastic products containing the notified chemical. However dermal exposure would be very low since the notified polymer is expected to be largely trapped within the polymeric matrix of the plastic products and unlikely to be bioavailable.

When used in accordance with the proposed manner in thermal plastic moulding, the risk to public health is not considered to be unreasonable.

In some uses the notified polymer will be in contact with food. No migration data were available, however food contact approval by the US FDA has been given for the polymer for all foods except:

- alcoholic foods;
- infant formula and breast milk;
- high temperature heat-sterilised;
- irradiation;
- cooking at temperatures exceeding 250°F.

As there could be food contact use, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

## **7. ENVIRONMENTAL RISK ASSESSMENT**

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will be imported for use in thermal plastic moulding operations. No release of the notified polymer to the aquatic environment is expected from manufacture and reformulation processes. Accidental spills during the reformulation process are expected to be collected and disposed of through approved waste management facilities in accordance with local government regulations. The notified polymer is expected to be physically incorporated within the inert polymer matrix. At the end of their useful life, articles containing the notified polymer are expected to be disposed of to landfill, in accordance with local government regulations. All wastes, including import container residues and empty containers, are expected to be disposed of through approved waste management facilities in accordance with local government regulations.

Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In landfill, the notified polymer is bound within a polymer matrix, and is not expected to be bioavailable or mobile. Due to its high molecular weight and expected low water solubility, the notified polymer is not expected to cross biological membranes and is, therefore, not expected to bioaccumulate. In landfill, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon.

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