

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in GS Pla® FD type

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/1410	Chemiplas Australia Pty Ltd	Polymer in GS Pla® FD type	No	< 300 tonnes per annum	Component of plastics

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.

- In the interest of occupational health and safety, the following precaution should be observed for use of the notified polymer in powder form with dust formation potential:
 - 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/m³.
- 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 formation is expected during handling.
- 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 a component of plastics, 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 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, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

GS Pla FD type (products containing the notified polymer at > 90%)

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	Solid pellets
Melting Point	80–110 °C
Density	1,200–1,300 kg/m ³
Water Solubility	Expected to be low based on the predominantly hydrophobic structure
Pellet Size	1–5 mm
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	30–60	50–100	< 300

Use

The notified polymer will not be manufactured in Australia. It will be imported in pellet form and used in thermal plastics for moulding materials, including materials for fibres, monofilaments, sheets, films, plastic shopping bags and garbage bags. It may be used for food contact applications. The notified polymer will be present in the final products at concentration up to 100% (neat form).

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 > 2,000 mg/kg bw	None	OECD TG 423
Genotoxicity - bacterial reverse mutation	non mutagenic	None	OECD TG 471

All results were indicative of low hazard.

The notified polymer is a high molecular weight polymer (Mn 10,000-70,000 Da) 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 used in a form with potential to release respirable particles. 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. Dermal and ocular exposure to products 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 if dust is formed during the processes. 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 dusts of the notified polymer are formed during processes, which have a respirable particle size, there is a risk of lung overloading from inhalation of the dusts. However inhalation is expected to be minimised by the industrial controls in place. Once cured/moulded, the notified polymer is encapsulated within the polymer matrix and not expected to be available for inhalation 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 come into 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 plastics for moulding materials, the risk to public health is not considered to be unreasonable.

The end use plastic articles containing the notified polymer may come into contact with food. Food contact approval by the US FDA has been given for the polymer for all foods under prescribed conditions of use, except for:

- alcoholic foods;
- infant formula and breast milk.

Based on the information provided in US FDA document, the notified polymer is not suitable for use with food contact under following conditions:

- high temperature heat-sterilised;
- boiling water sterilised;
- frozen or refrigerated storage: ready-prepared foods intended to be heated in container at time of use;
- irradiation;
- cooking at temperature exceeding 121 °C.

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 in a neat solid form and will be used in thermal injection moulding operations to manufacture plastic and polymer articles. The majority of the notified polymer will be used in the manufacture of plastic and polymer articles by extrusion or injection moulding, and therefore 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. Wastes including spilled material during production (estimated to be 1%), import containers containing residues (estimated to be 1%), and waste from processing of plastic articles at the end of their useful lives, are expected to be disposed of to landfill. Proportion of spilled and scrap material from extrusion and injection moulding may be melted and reprocessed. The import bags containing the notified polymer may be recycled or disposed to landfill. Therefore, no release of the notified polymer to the aquatic environment is expected during the production of plastic and polymer articles, use and disposal.

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 low solubility, the notified polymer is not expected to cross biological membranes and is, therefore, 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, based on its assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.