File No PLC/985

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN FULL PUBLIC REPORT

Modified Soarnol

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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

May 2011

Table of Contents

1. APPLICANT AND NOTIFICATION DETAILS

Applicant
Chemiplas Australia Pty Ltd (ABN: 29 003 056 808)
3/112 Wellington Parade,
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, use details, import volume and residual monomer content determination.

2. IDENTITY OF POLYMER

Marketing Name(s)
Modified Soarnol

Molecular Weight
Number Average Molecular Weight (Mn) is >10,000 Da

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

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 notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	White solid pellets
Melting Point/Glass Transition Temp	131 °C
Density	1170 kg/m^3 at 20 °C
Water Solubility	<0.004 g/L at 20 °C. Determined by measuring the dissolved organic carbon (DOC) concentration in the filtrate from aqueous dispersions (prepared as ≤ 2 g/L at pH 1.2, 4, 7 and 9). Test conducted in accordance with the Test Method 'Safety Evaluation Flow Scheme for Polymers' (METI, 2004).
Dissociation Constant	The notified polymer does not contain functionality that is expected to dissociate under environmental conditions.
Particle Size	Pellets >3 mm
Reactivity	Stable under normal environmental conditions. Tests were conducted at pH 1.2, 4, 7 and 9. Aqueous dispersions of notified polymer (1000 mg/L) were shaken at 40ºC for 14 days (24 h at pH 1.2) and examined for degradability by DOC and infrared (IR) absorption. The results indicated no

	significant difference from the starting material. The notified polymer does not contain any readily hydrolysable functionality and is therefore expected to be hydrolytically stable.
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤2	≤2	≤5	≤5	≤10

Use
The notified polymer will not be manufactured in Australia.
The notified polymer will be imported into Australia at 100% concentration in pellet form and used in extrusion processes. It will be used as a component of packaging material for food and agricultural chemicals. The notified polymer is intended to be used in industrial settings and will only be available to the general public in the form of finished articles. In the finished products, it will be layered within other materials and hence will not have direct contact with food.

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 notifier has supplied migration test data that showed the total non-volatile extractives (NVE) from a 30 µm bare film of the notified polymer conducted under equivalent hot-fill or pasteurisation conditions (100 °C for 30 min and 40 °C for 10 days) using isooctane as the fatty food simulant was less than the limit of quantification (i.e. <1 ppm). In addition, the residual monomer content for one of the 3 monomers that comprise the notified polymer was determined to be present at <10 ppm in the pellets. The residual monomer content would be expected to be further reduced once the pellets are converted into a film by extrusion.

Given the assumed low hazard, low residual monomer content and total NVE, the risk of the notified polymer to occupational and public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment. The majority of the notified polymer will be physically bound within the inert matrix of the extruded plastic containers, which are expected to ultimately be disposed of to landfill. During reformulation, spills, residues in import containers (up to 0.1% of the import volume) and scraps from the extrusion process (up to 1% of the import volume) are expected to be collected and recycled, or disposed of to landfill. Release of the notified polymer to the aquatic environment is not expected. In landfill, it is not expected to be bioavailable or mobile due to its high molecular weight and low solubility in water. 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, based on its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

8. RECOMMENDATIONS

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.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal
- The notified polymer should be disposed to landfill.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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 packaging 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 chemical 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 MSDS of the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.