File No PLC/823

April 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Santoprene Thermoplastic Rubber

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the 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 Department of the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Marplex Australia Pty Ltd (78 004 691 614)
221 - 239 Browns Road, Noble Park VIC 3174

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2008), US TSCA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Santoprene Thermoplastic Rubber General Purpose Grades

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10000 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:	Black or natural (colourable) rubber-like pellets
Melting Point/Glass Transition Temp	Melting point data is not available for the notified polymer itself. A representative grade of the product containing the notified polymer has a melting point of 155.68°C.
Density	900-1000 kg/m^3 (temperature unspecified)
Water Solubility	Stated to be insoluble, which is consistent with its crosslinked and hydrophobic chemical structure and high molecular weight.
Particle Size	The product containing the notified polymer is imported in the form of rubber pellets.
Reactivity	Stable under normal environmental conditions. Degradation of the notified polymer may occur due to overheating. The notified polymer may be incompatible with other polymers.
Degradation Products	Smoke, carbon monoxide, formaldehyde and possibly hydrocarbons may evolve when processing temperatures exceed 260°C, or when ignited.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	700	700	700	700	700

Use
This polymer is either directly processed or compounded with other materials to manufacture rubber goods/articles for the automotive & construction industries.

Mode of Introduction and Disposal
The pellet formulation containing the notified polymer (concentrations of 10-60%) will be imported through Melbourne or Brisbane in 25kg paper bags and 650kg octabins. Following importation, it will be transported throughout Australia by road or rail to end users.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the product containing the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rabbit, intracutaneous toxicity of solvent extracts*	No evidence of significant irritation or toxicity	yes	unknown
2. Rabbit, muscle implantation study*	No macroscopic reaction	no	unknown
3. Guinea pig, skin sensitisation of solvent extracts*	negative	no	unknown
4. Mice, systemic toxicity*	No significant evidence of systemic toxicity	yes	unknown

*Concentration ranging from 10-40%.

All results were indicative of low hazard.

Occupational Health and Safety Risk Assessment
Dermal exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited due to the largely automated processes, and the engineering controls and personal protective equipment likely to be used during such operations. In addition, the notified polymer is expected to be bound within the imported pellets and finished articles and thus exposure is unlikely.

Inhalation exposure to the notified polymer is unlikely to occur, given the relatively large size (pellets) of the imported material and the fact that dust is not expected to be generated.

The notified polymer may degrade to toxic gases, such as formaldehyde, at high temperatures (though not under normal use conditions). If degradation was to occur due to increases in operating temperatures, precautions should be taken to ensure that worker exposure to formaldehyde remains below the exposure standard levels specified[1].

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer.

[1]ASCC (2008) Benchmarking of exposures to wood dust and formaldehyde in selected industries in Australia. Office of the Australian Safety and Compensation Council, Australian Government Publishing Service, Canberra.

Public Health Risk Assessment
Members of the public may make dermal contact with a range of articles containing the notified polymer. However, exposure is expected to be low because the notified polymer will be bound within a matrix and is unlikely to be bioavailable. Therefore, the risk to public health will be low, given that exposure is low and the notified polymer is likely to be of low hazard.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Risk Assessment
No significant release of the notified polymer is expected given the reported use pattern. Therefore, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Specific engineering controls, work practices or personal protective equipment 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.

- Control measures should be implemented to prevent overheating and avoid contact of Santoprene Thermoplastic Rubber with incompatible polymers.

- Employers should ensure that NOHSC exposure standards for the degradation product formaldehyde are not to be exceeded in the workplace.

- 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.

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.

Regulatory Obligations

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.
- the notified polymer is introduced in powder form.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from manufacture of rubber goods/articles for the automotive & construction industries, 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 products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.