

File No PLC/730

December 2007

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

FULL PUBLIC REPORT

Formaldehyde, polymer with ethene, 5-ethylidenebicyclo[2.2.1]hept-2-ene, 1-propene and 4-(1,1,3,3-tetramethylbutyl)phenol

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 and Water Resources.

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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION.....	5
6. HUMAN HEALTH IMPLICATIONS.....	5
Hazard Characterisation.....	5
Occupational Health and Safety Risk Assessment.....	5
Public Health Risk Assessment	6
7. ENVIRONMENTAL IMPLICATIONS	6
Hazard Characterisation.....	6
Environmental Risk Assessment.....	6
8. CONCLUSIONS AND RECOMMENDATIONS.....	6
Human health risk assessment	6
Environmental risk assessment	6
Recommendations.....	7
Regulatory Obligations	7

FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Orica Australia Pty Ltd (ABN: 99 004 117 828)
1 Nicholson Street
Melbourne VIC 3000

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

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

Korea (2007)
China (2007)
US TSCA
Canada (confidential DSL listing)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Santoprene Thermoplastic Rubber General Purpose Grades (containing < 60% notified polymer)

CHEMICAL NAME

Formaldehyde, polymer with ethene, 5-ethylidenebicyclo[2.2.1]hept-2-ene, 1-propene and 4-(1,1,3,3-tetramethylbutyl)phenol

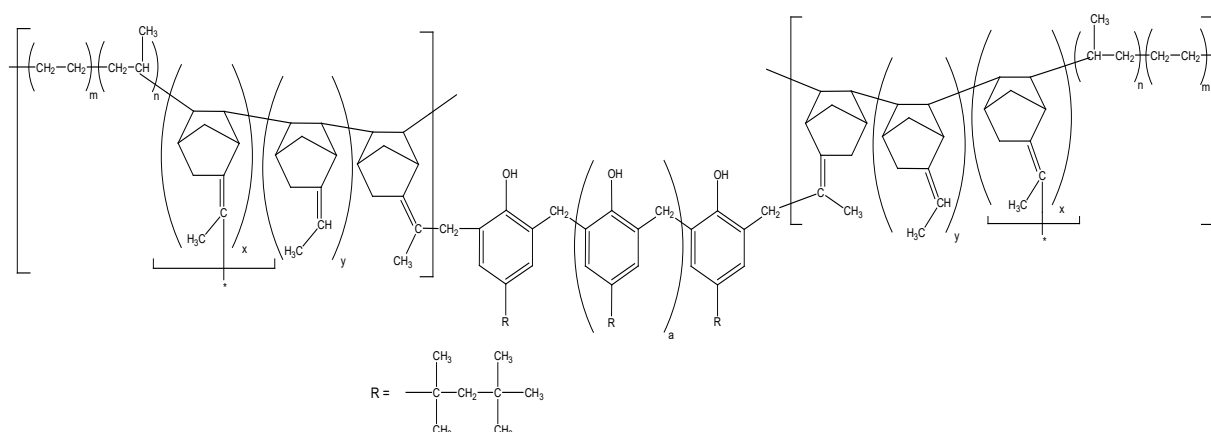
CAS NUMBER

137175-50-9

MOLECULAR FORMULA

(C₁₄H₂₂O.C₉H₁₂.C₃H₆.C₂H₄.CH₂O)_x

STRUCTURAL FORMULA

**MOLECULAR WEIGHT ***

Number Average Molecular Weight (Mn)	166,323 Da
Weight Average Molecular Weight (Mw)	433,611 Da
Polydispersity Index (Mw/Mn)	2.61
% of Low MW Species < 1000 Da	0
% of Low MW Species < 500 Da	0

* Data for a starting polymer (CAS number 25038-36-2). The notified polymer is expected to have higher molecular weight.

POLYMER CONSTITUENTS

Chemical Name	CAS No.	Weight % starting	Weight % residual
Ethene	74-85-1	> 66	Not detected
1-Propene	115-07-1	< 32	Not detected
Bicyclo[2.2.1]hept-2-ene, 5-ethylidene-	16219-75-3	< 5	Not detected
Formaldehyde, polymer with 4-(1,1,3,3-tetramethylbutyl)phenol	26678-93-3	< 5	< 3**

Tin chloride (catalyst, CAS number 7772-99-8)

**The notifier has indicated that this a conservative estimate, and the actual figure is likely to be lower. In addition, it is expected that any residuals of this reactant will be encapsulated within the cross-linked polymer structure and are unlikely to be released during normal conditions of use.

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met (yes/no/not applicable)
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	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	920 - 980 kg/m ³ (MSDS)
Water Solubility	Claimed to be insoluble, which is consistent with its hydrophobic chemical structure.
Particle Size	The product containing the notified polymer is imported in the form of rubber pellets approximately 3 mm in diameter.
Reactivity	Stable under normal conditions of use
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

Mode of Introduction

The finished product containing the notified polymer (concentrations of < 60%) will be imported by air or sea into Melbourne or Brisbane in 25kg plastic bags. Following importation, it will be transported throughout Australia by road or rail to end users.

Use

The notified polymer will be used in mechanical rubber articles, largely for the automotive and construction industries, but other uses include: appliances, business machines, electrical/electronic components, fluid delivery, food contact, hardware, sporting goods, consumer products, etc. The notified polymer will also be used in medical devices, however, this assessment certificate covers only industrial uses and does not infer approval for supply of medical device products that contain the notified chemical. Medical devices are considered to be therapeutic goods within the meaning of the *Therapeutic Goods Act 1989*.

The imported pellets containing the notified polymer will be extruded, injection moulded, or blow moulded into final products at temperatures of ~200 °C.

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 a typical product containing the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >5000 mg/kg bw	no	unknown
2. Rat, acute dermal	LD50 >5000 mg/kg bw	yes	unknown
3. Rabbit, skin irritation	slightly irritating	yes	unknown
4. Rabbit, eye irritation	slightly irritating	yes	unknown

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 of the imported pellets 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 for formaldehyde.

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.

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 should 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

Environmental Release

The notified polymer is imported into Australia as a component embedded in the product "Santoprene™ General Purpose Rubber" which is in pellet form. This product having the notified polymer is then used in the manufacture of various moulded, extruded and blow moulded articles for supply into the automotive, industrial and consumer industries. During the moulding process a small amount of Santoprene™ General Purpose Rubber may be spilled or lost. The pellets will be shaken out of the packaging. Further small losses may also occur during the moulding process from cleaning and servicing of equipment and from scrap parts produced during moulding. The scrap parts can be recycled within the process and therefore minimise waste.

Losses at this stage would be low due to the recyclable nature of the material. The notified polymer may be recycled several times for similar applications and any waste or losses would be collected and disposed of to landfill.

Environmental Fate

As mentioned above, the notified polymer is neither available in free form nor expected to be released from the final imported product (Santoprene™ General Purpose Rubber) or from the moulded articles. The notified polymer as a component of Santoprene™ General Purpose Rubber will share the same fate as the products into which it is moulded or extruded. The products, which include automotive seals, extruded window gaskets, soft touch toothbrush handles, and various "rubber" products, will be placed into landfill at the end of the useful life of the product.

The notified polymer is not available in free form at any stage of its lifecycle in Australia and hence is unlikely to be released to the aquatic environment. Therefore, the notified polymer is unlikely to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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.

- 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 polymer has changed from use in rubber articles (largely automotive and construction, as well as consumer products), or is likely to change significantly;
 - the amount of polymer being introduced has increased from 700 tonnes per annum, or is likely to increase, significantly;
 - if the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the 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.

No additional secondary notification conditions are stipulated.

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.