

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Carbonic acid, compd. with guanidine (1:2), polymer with 1,6-diisocyanatohexane

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

July 2015

Table of Contents

SUMMARY	2
CONCLUSIONS AND REGULATORY OBLIGATIONS.....	2
ASSESSMENT DETAILS.....	4
1. APPLICANT AND NOTIFICATION DETAILS.....	4
2. IDENTITY OF POLYMER	4
3. PLC CRITERIA JUSTIFICATION	6
4. PHYSICAL AND CHEMICAL PROPERTIES.....	6
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH RISK ASSESSMENT.....	6
7. ENVIRONMENTAL RISK ASSESSMENT	7

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1283	Symrise Pty Ltd	Carbonic acid, compd. with guanidine (1:2), polymer with 1,6-diisocyanatohexane	No	≤ 0.6 tonne per annum	Component of fragrances

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.

- A copy of the (M)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;
 - the notified polymer is introduced in powdered form;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of fragrances, 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.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS**1. APPLICANT AND NOTIFICATION DETAILS****Applicants**

Symrise Pty Ltd (ABN: 67 000 880 946)
168 South Creek Road
Dee Why NSW 2099

Exempt Information (Section 75 of the Act)

No details are claimed exempt from publication.

2. IDENTITY OF POLYMER**Marketing Name**

SymCap® G (product containing notified polymer at ~2% concentration)

Chemical Name

Carbonic acid, compd. with guanidine (1:2), polymer with 1,6-diisocyanatohexane

CAS Number

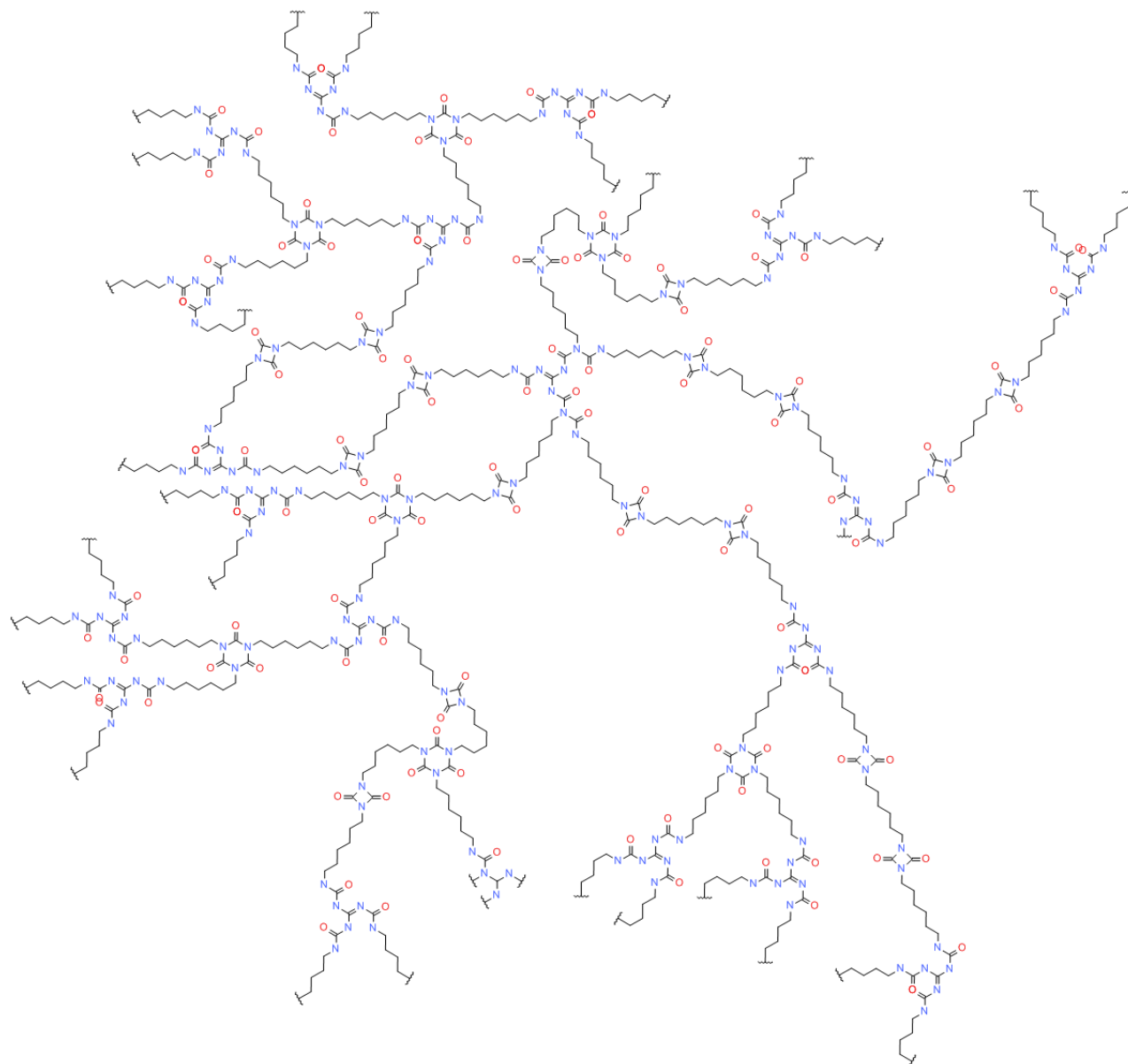
164457-81-2

Molecular Formula

$(C_8H_{12}N_2O_2 \cdot CH_5N_3 \cdot \frac{1}{2}CH_2O_3)_x$

Structural Formula

Representative structure of SymCap G



The notified polymer is expected to be terminated by amine or isocyanate groups.

Molecular Weight

Number Average Molecular Weight (Mn)

Estimated to be >> 10,000 Da

Weight Average Molecular Weight (Mw)

Estimated to be >> 10,000 Da

Polydispersity Index (Mw/Mn)

Not determined

% of Low MW Species < 1000 Da

Estimated to be very low

% of Low MW Species < 500 Da

Estimated to be very low

Polymer Constituents

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Hexane, 1,6-diisocyanato-, homopolymer	28182-81-2	~75	~ 0
Carbonic acid, compound with guanidine (1:2)	593-85-1	~25	0.13

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 powder
Melting Point/Glass Transition Temp	Not determined
Density	Not determined
Water Solubility	Insoluble
Particle Size	d10: 2-4 µm d50: 12-20 µm d90: 28-46 µm Respirable fraction (< 10 µm): 18-40%
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	0.2-0.3	0.3-0.4	0.3-0.5	0.4-0.6	0.4-0.6

Use

The notified polymer will be used for microencapsulation of fragrances. The notified polymer will be imported into Australia either: (1) as a component of a formulation (at ~2% concentration) for reformulation into cosmetic and household products for consumer use; or (2) as a component of finished cosmetic and household products (at < 0.002% concentration).

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>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

The result was indicative of low hazard.

The notified polymer is a high molecular weight polymer (possibly > 70,000 Da) with low water solubility. The particle size of the notified polymer indicates that a portion (18-40%) will be respirable (< 10 µm). Inhalation 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. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

Occupational Health and Safety Risk Assessment

Powdered notified polymer will not be handled by reformulation workers in Australia. The notified polymer will be introduced in liquid formulation for reformulation into cosmetic and household products; hence inhalation exposure is not expected. Furthermore, transfer, blending and packaging processes are expected to be highly automated and fully enclosed.

Therefore, given the assumed low hazard and the assessed use pattern, the risk of the notified polymer to occupational health and safety is not considered to be unreasonable.

Public Health and Safety Risk Assessment

The notified polymer may be used in aerosol products; however, given the very low concentrations of the notified polymer in consumer products ($< 0.002\%$), inhalation exposure is very limited.

Therefore, under the proposed use scenario, the risk of the notified polymer to public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers with a potential cationic density may have adverse effects on aquatic life. However, given the insolubility of the notified polymer in water, which limits its potential to ionise in the environment, the notified polymer is not expected to reach ecotoxicologically significant concentrations.

The notified polymer will be imported into Australia as a component of fragrance preparations for local reformulation into a variety of consumer products (personal care products, household products). The notified polymer will also be imported as a component of finished consumer products. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers. These releases are expected to be collected and disposed of in accordance with local government regulations.

Based on its use in consumer products, it is expected that the majority of the notified polymer will be released to the aquatic compartment through sewers during use. Under a worst case scenario, it is assumed that 100% of the notified polymer will be washed into sewers. The resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated at $0.36 \mu\text{g/L}$ [$\text{PEC river} = 1.64 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 22.613 \text{ million people}) \times 1$ (dilution factor)]. The PEC is below the EC50 for algae of the most toxic polymers ($\text{EC50} > 1 \text{ mg/L}$). In sewage treatment processes, very little of the notified polymer is expected to partition to the supernatant water, due to its high molecular weight and low solubility in water. Based on its high molecular weight and low water solubility, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate.

All wastes including container residues are expected to be disposed of to landfill. Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In either surface waters or landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

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.