

File No: SAPLC/86

25 July 2008

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

FULL PUBLIC REPORT

Polymer in Sunsppheres (Styrene/Acrylate Copolymer)

This Self 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**

Part 2 –PLC Self Assessment**Polymer in Sunspheres (Styrene/Acrylate Copolymer)****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Rohm and Haas Australia Pty. Ltd. (ABN 29 004 513 188)
4th Floor, 969 Burke Road
Camberwell, VIC. 3124.

NOTIFICATION CATEGORY

Self Assessment: Polymer of Low Concern

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,

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, 2007

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Sunspheres Powder, Sunspheres PGL

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) >10000 Da.

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

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 (solid form)
Milky white suspension

Melting Point

>100°C

Density

2,350 to 2,500 kg/m³ at 25°C

Water Solubility	5.6 mg/L (pH 7, 37°C) (Korean Polymer Test Guideline)
Particle Size	1.4 micrometer diameter (Mass Median Aerodynamic Diameter) 98% <5.27 µm.
Reactivity	Stable under normal environmental conditions. The notified polymer contains potentially hydrolysable groups but hydrolysis is not expected to occur in the environmental pH range of 4-9.
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>
<i>Tonnes</i>	1	2	3	4	5

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a 25% w/w component of the Sunsppheres PGL product in water and as an 85% w/w component of the Sunsppheres Powder product. The notified polymer will not be manufactured in Australia.

Currently no customers have been established for the product. However, it is expected that up to 5 customers throughout Australia will be identified.

The imported Sunsppheres products containing the notified polymer will be imported in 215 kg plastic drums and 20 kg steel pails. Upon arrival at ports in Sydney and/or Melbourne the notified polymer will be transported by road to the notifier's warehouse where it will be stored under cover until such time that it is transported to customers throughout Australia.

Reformulation processes

At the reformulator, the product will be formulated into personal care products (such as makeup) with SPF<4. These products will contain up to 5.0% w/w of the notified polymer.

Typically during reformulation, the notified polymer will be manually weighed and then poured directly into a blending vessel with the aid of a mechanical lifting device. Once blended with other ingredients and converted into the finished product, it will be packaged into a variety of plastic containers of up to 1 litre capacity for sale to both beauty salons and the general public.

Use

The notified polymer is to be used to enhance the efficiency of UV absorbers and/or used as an opacifier in the formulation of personal care products such as makeup with a SPF<4.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and warehousing workers may come into dermal, inhalation and ocular contact with the notified polymer through accidental leaks and spillages of the drums and containers.

Typically during reformulation, workers will manually weigh and transfer the polymer powder or emulsion to the mixing vessel. Workers handling the emulsion form will wear impermeable gloves, eye protection and coveralls. In addition, workers handling the powder form will wear dust respirators. Those workers handling the notified polymer in powder form will do so in areas where local exhaust ventilation will further reduce the potential for inhalation exposure.

Typically during filling of personal care product packaging, the product will be pumped from holding tanks to the automated filling equipment. Filling line workers will wear impermeable gloves, eye protection and coveralls. Exposure to the notified polymer to these workers can occur from spills and drips during filling line operation and cleaning. Exposure will be by either dermal or ocular routes, however significant exposure will be limited due to the workplace practices and personal protective equipment used.

Some personal care products will be used in beauty salons where workers will come into contact with the notified polymer via dermal or ocular routes during application of the end use product.

PUBLIC EXPOSURE

Widespread public exposure is expected as the products containing <5% of the notified polymer are intended for use in personal skin care products and will be widely available to consumers. Members of the public are likely to experience dermal exposure as a result of using the products, which may be applied to the skin up to twice per day with between 1- 10 g of the product being applied with each use. In addition, there may be accidental ocular exposure as well as unintentional ingestion of small quantities of the products.

6.2. Toxicological 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 notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >5,000 mg/kg bw (as 25% polymer emulsion)	no	no	OECD TG 401
2. Rabbit, acute dermal	LD50 >5,000 mg/kg bw (as 25% polymer emulsion)	no	no	OECD TG 402
3. Rat, acute inhalation	LC50 5.3 mg/L/4 hour (as 100% polymer powder)	no	yes	OECD TG 403
4. Rabbit, skin irritation	non-irritating (as 25% polymer emulsion)	no	no	OECD TG 404
5. Rabbit, eye irritation	non-irritating (as 100% polymer powder)	no	yes	OECD TG 405
6. Skin sensitisation – Repeated Insult Patch Test - Human	no evidence of sensitisation. (as 25% polymer emulsion)	no	no	non-standard test protocol
7. Genotoxicity - bacterial reverse mutation	non mutagenic (as 25% polymer emulsion)	no	no	OECD TG 471

All results were indicative of low hazard.

Observed Effects:

Eye Irritation

Conjunctivitis was observed at 1 and 24 hours in all rabbits but was no longer evident by 48 hours.

Acute Inhalation

Rales were noted for one male immediately following exposure. There were no other toxicologically relevant clinical observations. All animals were considered normal on the day following exposure.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

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

However, of main concern to the health of workers is the risk from inhalation exposure to the notified polymer, due to the potential adverse health effects of respirable insoluble particulates. Water insoluble high molecular weight polymers in the respirable particle size range (<10 µm) have the potential to cause lung overloading.

The workers who will be potentially exposed to the powder form of the notified polymer are mainly reformulation operators, and these workers face the greatest potential risk of adverse health effects arising from exposure. Inhalation exposure to the notified polymer could occur during manual transfer of the powder for blending.

The Australian recommended exposure standard for nuisance dust is 10 mg/m³ [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

Exposure to the notified polymer in powder form is expected to be minimised by exhaust ventilation and the use of appropriate respirators as required.

The overall OHS risk presented by the notified polymer is not expected to be unacceptable, based on low hazard demonstrated by the toxicological investigations and the anticipated use of control measures and personal protective equipment by workers to minimise exposure.

PUBLIC HEALTH

Members of the public who use personal care products containing the notified polymer will make dermal contact and possible accidental ocular contact with the notified polymer. Accidental ingestion is also possible. However, the risk to public health is not considered to be unacceptable because the polymer presents a low health hazard as demonstrated by toxicological investigations in animals, is present at low concentrations (<5%) and is unlikely to cross biological membranes due to its high molecular weight. Residual monomers are present at levels unlikely to present a risk to public health once incorporated into the finished personal care product.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the drums or steel packaged containers.

During formulation and packaging, spills are expected to be minimal. When spills occur, they will be contained by bunding, collected with absorbent material and sent to a licensed off site waste disposal centre. Empty drums from import will be sent to drum reconditioners.

Cleaning of manufacturing and packaging equipment will be performed by flushing with water. Typically, cleaning water and product residues will be transferred to the on site waste treatment facility where solids will be precipitated and later disposed of to a licensed waste landfill site.

The total amount of waste polymer produced during reformulation and packaging due to spills, drum residues and cleaning is expected to be approximately 3% or 150 kg of the maximum import volume. Approximately 5% or 250 kg of the notified polymer will remain as residues in consumer packaging and will be disposed of to landfill via domestic waste.

All of the remainder of the notified polymer will be used in personal care products that are applied to the skin.

Of this 4,600 kg of the notified polymer, it is estimated that approximately 40% will be removed from the skin with disposable tissues etc and disposed of to landfill via domestic waste and 60% will be released to sewerage systems throughout Australia through washing of skin.

ENVIRONMENTAL FATE

The notified polymer is expected to be hydrolytically stable and is not expected to be readily biodegradable. Due to the high molecular weight of the notified polymer it is not expected to cross biological membranes or bioaccumulate.

The notified polymer has low solubility in water and is not expected to be readily mobile in aquatic and terrestrial compartments. Due to its hydrophobic nature, the notified chemical is likely to be further immobilised via association with organic phases in soil and sediments in landfill and sewage treatment plants, eventually degrading through biotic and abiotic processes to form water and oxides of carbon.

7.2. Environmental Hazard Characterisation

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

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline (Choose one)</i>
Fish Toxicity	EC50 (96 hr) >100 mg/L NOEC > 100 mg/L	no	OECD TG 203
Daphnia Toxicity	(as 37.5% polymer emulsion) EC50 (48 hr) >100 mg/L NOEC > 100 mg/L	no	OECD TG 202
Algal Toxicity	(as 37.5% polymer emulsion) EC50 >100 mg/L NOEC > 100 mg/L	no	OECD TG 201
Inhibition of Bacterial Respiration	(as 37.5% polymer emulsion) EC50 >100 mg/L (as 100% polymer)	no	OECD TG 209

All results were indicative of low hazard.

7.3. Environmental Risk Assessment

All of the imported notified polymer will eventually be released into the environment. Up to 2,000 kg will be released to landfill via spills, cleaning equipment and packaging residues. The remainder, or up to 3,000 kg, will be discharged into sewerage systems after washing skin.

Personal care products containing the notified polymer will be used throughout Australia and release will be diverse. Therefore release of the notified polymer is unlikely to exist at levels that could pose a threat to the environment.

8. CONCLUSIONS**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.

Environmental risk assessment

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

9. RECOMMENDATIONS**CONTROL MEASURES****Occupational Health and Safety**

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
 - The level of atmospheric nuisance dust should be maintained as low as possible. The American Conference of Governmental Industrial Hygienists (ACGIH) recommended

exposure limit of 3 mg/m³ for “respirable (insoluble) particulates (not otherwise regulated)” should be observed.

- As there is a risk of permanent lung damage from inhalation of dusts, employers should ensure local exhaust ventilation is present or dust masks (suitable for respirable particles) are used when handling the dry powder form of the notified polymer during reformulation.

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

- Avoid the generation of airborne dusts.
- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- Spillages and container residues containing notified polymer should be disposed of to landfill and/or liquid waste treated on-site or collected by licensed waste contractors for treatment at authorised waste treatment plants.

Emergency procedures

- Spills and/or accidental release of the imported product containing the notified polymer should not be allowed into drains or waterways. Liquid spills should be handled by absorbing with sand or other inert absorbent material and put into suitable container for disposal.

10. 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 personal care products with SPF<4; or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 5 tonnes per annum, or is likely to increase, significantly;
 - if 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of the notified polymer and/or products containing the notified polymer was/were provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.