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September 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PEG-40 Sorbitan Perisostearate

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

PEG-40 Sorbitan Perisostearate

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Beiersdorf Australia Ltd. (ABN: 98 000 025 623)
4 Khartoum Rd, North Ryde, NSW 2113

NOTIFICATION CATEGORY
Self Assessment: Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Other Names, Molecular Formula, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, and Import Volume.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

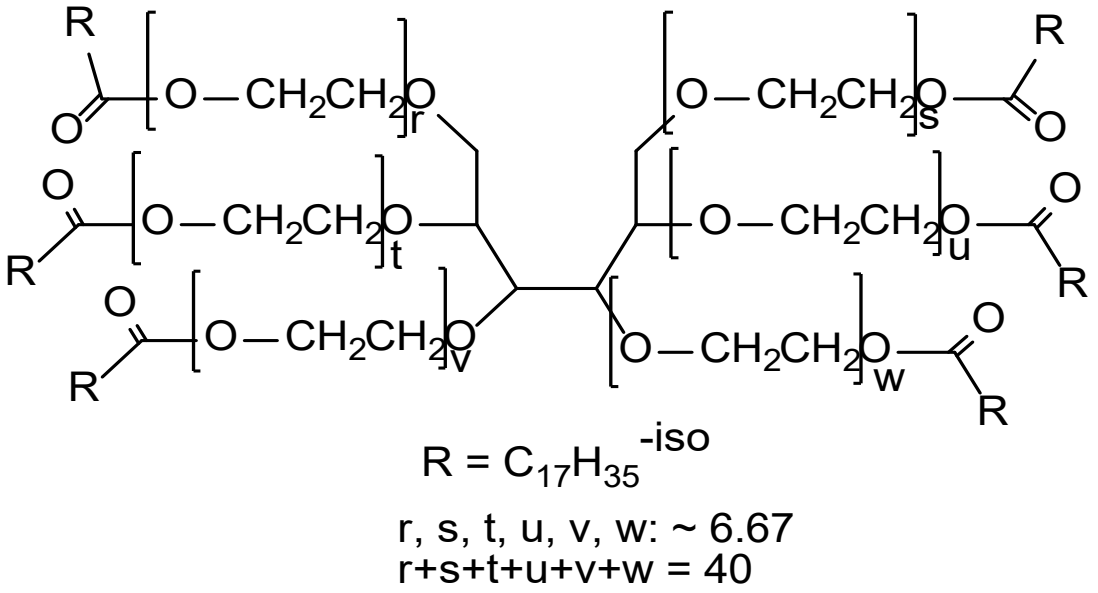
NOTIFICATION IN OTHER COUNTRIES
USA (TSCA)
Canada (DSL)
P.R. China (IECSC)
Japan (ENCS)
Korea (KECL)
NZ (NZIOC)
Philippines (PICCS)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Sorbitan, isooctadecanoate, poly(oxy-1,2-ethanediyl) derivs.

CAS NUMBER
58205-96-2

STRUCTURAL FORMULA



R = $C_{17}H_{35}$-iso

r, s, t, u, v, w: ~ 6.67
r+s+t+u+v+w = 40

MARKETING NAME
TEGO SIS 40
PEG-40 Sorbitan Perisostearate (INCI Name)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (NAMW) > 1000

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	Yellow Liquid
Melting Point/Glass Transition Temp	Not measured
Density	1000 kg/m^3 at 25°C
Water Solubility	Not measured. Refer to comments section.
Reactivity	Stable under normal environmental conditions. The notified polymer contains hydrolysable functionalities, however, hydrolysis is unlikely to occur at the environmental pH range of 4-9.
Degradation Products	None under normal conditions of use

Comments
Water Solubility - Due to the intrinsic properties of the notified polymer only stable emulsions (with micelles) are formed. This means that the water solubility of the notified polymer cannot be determined according to OECD guideline 105 with the column method.

5. INTRODUCTION AND USE INFORMATION

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

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

USE AND MODE OF INTRODUCTION AND DISPOSAL
Mode of Introduction
The notified polymer will be imported as a component of fully formulated finished cosmetic products at less than 10%.

Finished cosmetic products containing the polymer will be imported into mainly Port Botany, Sydney where they will be transported to storage at the Beiersdorf warehouse in Huntingwood, NSW.

The finished products will be imported in a variety of cosmetic containers suitable for sale. These containers will be packed in cartons, 12 of which will be packed to a cardboard shipper.

Use
The notified polymer will be used as an emulsifying agent in cosmetic products at a level of less than 10%

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE
Dockside and warehouse workers will be involved in transporting finished products from the wharf to the central distribution centre. At the warehouse pallets of the product will be moved to and from storage shelving. Stock may be re-packed to fill smaller orders which are then transported to a retailer's central distribution depot.

Dockside and warehouse workers are not expected to have any contact with the notified polymer, except in the case of a spill. However, they are expected to wear uniforms and safety shoes to limit any potential for exposure.

PUBLIC EXPOSURE
Since the notified polymer will be in cosmetic products sold to the general public, widespread dermal and ocular exposure is expected. Exposure to the polymer will vary depending on individual use patterns. If used at its maximum, the typical daily use would be expected to be 10 – 20mL of product containing less than 10% notified polymer.

6.2. Toxicological Hazard Characterisation
No toxicological data submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY
The OH&S risks presented by the notified polymer are expected to be low. This is based on the minimal exposure to workers and the assumed low hazard of the notified polymer.

PUBLIC HEALTH

Widespread dermal exposure is expected during use. Accidental ocular exposure is also a possibility. Given the concentration of the polymer in the formulation is low and the toxicity of the notified polymer is assumed to be low, the risk to the general public is not expected to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Neither manufacturing nor formulation of the notified polymer will occur in Australia. Environmental releases from these processes are therefore not expected.

The formulated product will be applied to the skin. Therefore, the majority of the notified polymer is expected to enter the sewer via bathroom washing. The residues of the notified polymer are expected to be minimal and will be disposed of to landfill with the empty containers.

ENVIRONMENTAL FATE

The notified polymer is expected to be stable under normal environmental conditions. The potential for bioaccumulation is expected to be low based on the high molecular weight of > 1000 for the notified polymer.

Most of the notified polymer will be released into sewage after use. Due to its surfactant properties, a significant percentage of the notified polymer may remain in the water column, and the rest will be removed during sewage treatment and released to landfill.

7.2. Environmental Hazard Characterisation

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

7.3. Environmental Risk Assessment

Most of the notified polymer will be washed off the skin and into the sewer. If imported at the full 10 tonnes per year, based on a worst-case scenario with no removal of the notified polymer in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 6.4 µg/L.

Amount entering sewer annually 9900 kg
Population of Australia 21.161 million
Amount of water used per person per day 200 L
Number of days in a year 365

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified polymer in freshwater and marine water may approximate 6.4, 0.64 µg/L, respectively.

STP effluent re-use for irrigation occurs throughout Australia.

In either landfill or field, the notified polymer will undergo slow biotic and abiotic degradation process, forming water and oxides of carbon.

Based on the above, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment based on the reported use pattern.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the prescribed conditions of the occupational settings.

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided a MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. 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 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

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

10.1. 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.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from an emulsifying agent in cosmetic or personal care products; 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 a product 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.