

File No PLC/917

March 2010

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

FULL PUBLIC REPORT

PEG-20 Glyceryl Triisostearate

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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FULL PUBLIC REPORT**PEG-20 Glyceryl Triisostearate****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Unilever Australia Ltd (ABN: 66 004 050 828)
20 Cambridge St.
Epping NSW 2121

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)

Variation to the schedule of data requirements is claimed as follows: Melting Point/Glass Transition Temperature, Density, Water Solubility, Dissociation Constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

PEG-20 Glyceryl Triisostearate

CHEMICAL NAME

Poly(oxy-1,2-ethanediyl),.alpha.,.alpha.',.alpha.''-1,2,3-propanetriyltris[.omega.-[(1-oxoisooctadecyl)oxy]-

CAS NUMBER

86846-21-1

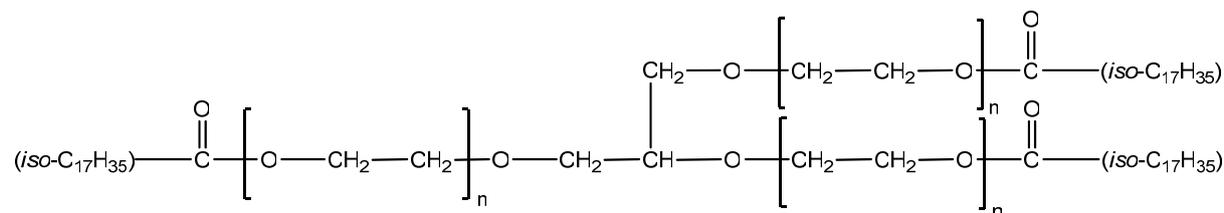
OTHER NAME(S)

Uniox GT-201S

MOLECULAR FORMULA

$(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_nC_{57}H_{110}O_6$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	1,484 Da
Weight Average Molecular Weight (Mw)	1,535 Da
Polydispersity Index (Mw/Mn)	1.03
% of Low MW Species < 1000 Da	3%
% of Low MW Species < 500 Da	<1%

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
1,2,3-Propanetriol	56-81-5	5	Estimated <1%
Oxirane	75-21-8	48	Estimated <0.0001%
Isooctadecanoic acid	30399-84-9	47	Estimated <2%

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	Colourless to pale-yellow liquid.
Melting Point/Glass Transition Temp	Not determined, congeals below 0 °C.
Density	Not determined, specific gravity (MSDS): 1000 kg/m ³ at 40/4 °C.
Water Solubility	Not tested. The notified polymer is expected to be surface active and be water dispersible due to the combination of hydrophobic endgroups on a hydrophilic polymer backbone.
Reactivity	Stable under normal environmental conditions. The notified polymer contains functional groups that are expected to hydrolyse very slowly in the environmental pH range (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>
Tonnes	2	2	2	2	2

Use

The notified polymer acts as an emulsifier, dispersing agent or solubilising agent in cosmetic and personal care products. It is intended for use by consumers in both rinse-off cleansing products (at levels up to 20%, e.g. foaming makeup remover) and leave-on products (at levels up to 5%, e.g. creams and lotions).

Mode of Introduction and Disposal

The notified polymer will be imported into Australia *via* Sydney ports as a raw material and as a component of rinse-off and leave-on cosmetic and personal care products. Where the raw material is imported, it will be added to formulated cosmetic products.

6. HUMAN HEALTH IMPLICATIONS

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 analogue chemicals (see below).

The following information was provided for analogues of the notified polymer. All information was obtained from literature reports, complete study reports were not provided to NICNAS.

	Glyceryl Triisostearate	Sorbitan Sesquiosostearate	PEG-20 Sorbitan Fatty Acid Esters
Rat, acute oral	LD ₅₀ >2000 mg/kg bw	LD ₅₀ >25000 mg/kg bw	LD ₅₀ >2000 mg/kg bw
Skin Irritation	Non-irritant, rabbit	Weak irritant, guinea pig	Non-irritant
Skin Sensitisation	Non-sensitising, guinea pig	Non-sensitising, RIPT human (Sorbitan fatty acid esters)	Non-sensitising, RIPT human
Eye Irritation	Non-irritant, rabbit	Mild irritant, rabbit	Mild irritant
Mutagenicity	Not mutagenic	Not available	Not mutagenic
Reference	CIR(2001)	CIR(2002)	CIR(2000)

Occupational Health and Safety Risk Assessment

As the notified polymer may be imported as the raw material and/or in finished products, the following refers to local reformulation processes.

Dermal and ocular exposure to the notified polymer may potentially occur during certain processes at the reformulation site. These processes include weighing of the notified polymer prior to reformulation, addition of the polymer into the mixing tank, quality assurance and packaging. However, exposure to significant amounts of the notified polymer is expected to be limited because of the automated processes, the engineering controls and personal protective equipment worn by workers.

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

Public Health Risk Assessment

The notified polymer will be present in cosmetic and personal care products at conc. <20%. Dermal exposure to the notified polymer is expected to be extensive but will vary depending on individual use patterns. Although the public will be exposed to the notified polymer during use of cosmetic and personal care products, the risk to public health is not considered to be unacceptable due to the predicted low hazard of the notified polymer.

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

The majority of the notified polymer is expected to be released to the sewer when it is washed from the skin. The predicted environmental concentration in rivers receiving effluent from sewage treatment works that allow complete passage of the maximum annual import quantity (2000 kg) can be estimated as 1.29 µg/L based on standard assumptions regarding water use by the Australian population. However, nonionic polymers with MW >1000 are likely to be removed from the water column by up to 90% by partitioning to solids during water treatment processes (Boethling and Nabholz, 1996). A predicted no-effect concentration (PNEC) cannot be calculated as ecotoxicological data have not been submitted. The notified polymer is not expected to bioaccumulate due to its high molecular weight. Up to 4% of the total import volume of the notified polymer will be disposed of to landfill as residue remaining in containers. In landfill the notified polymer is expected to partition to solids, where it is likely to undergo biotic and abiotic degradation processes to form water and oxides of carbon.

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 expected to pose a risk to the environment.

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 used in the formulation process.

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 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.
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of 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 the notified polymer (and a product containing the notified polymer) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

BIBLIOGRAPHY

Boethling RS & Nabholz JV (1996) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold, pp 187–234.

CIR (2000) Final Report on the Safety Assessment of PEG-20 Sorbitan Cocoate; PEG-40 Sorbitan Diisostearate; PEG-2, -5, -20 Sorbitan Isostearate; PEG-40 and -75 Sorbitan Lanolate; PEG-10, -40, -44, -75, and -80 Sorbitan Laurate; PEG-3 and -6 Sorbitan Oleate; PEG-80 Sorbitan Palmitate; PEG-40 Sorbitan Perisostearate; PEG-40 Sorbitan Peroleate; PEG-3, -6, -40, and -60 Sorbitan Stearate, PEG-20, -30, -40, and -60 Sorbitan Tetraoleate; PEG-60 Sorbitan Tetrastearate; PEG-20 and -160 Sorbitan Triisostearate; PEG-18 Sorbitan Trioleate; PEG-40 and -50 Sorbitol Hexaoleate; PEG-30 Sorbitol Tetraoleate Laurate; PEG-60 Sorbitol Tetrastearate – Addendum to the Final Report on the Safety Assessment of Polysorbates. Cosmetic Ingredient Review Expert Panel, Journal of the American College of Toxicology, IJT 19 (Suppl. 2) 2000.

CIR (2001) Final Report on the Safety Assessment of Trilaurin, Triarachidin, Tribehenin, Tricaprin, Tricaprylin, Trierucin, Triheptanoin, Triheptylundecanoin, Triisononanoin, Triisopalmitin, Triisostearin, Trilinolein, Trimyrustin, Trioctanoin, Triolein, Tripalmitin, Tripalmitolein, Triricinolein, Tristearin, Triundecanoin, Glyceryl Triacetyl Hydroxystearate, Glyceryl Triacetyl Ricinoleate and Glyceryl Stearate Diacetate. Cosmetic Ingredient Review Expert Panel, Journal of the American College of Toxicology, IJT 20 (Suppl. 4) 2001.

CIR (2002) Final Report on the Safety Assessment of Sorbitan Caprylate, Sorbitan Cocoate, Sorbitan Diisostearate, Sorbitan Dioleate, Sorbitan Sesquiosostearate, Sorbitan Sesquisteate, and Sorbitan Triisostearate. Cosmetic Ingredient Review Expert Panel, Journal of the American College of Toxicology, IJT 21 (Suppl. 1) 2002.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.