

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Decanedioic acid, polymer with 12-hydroxyoctadecanoic acid and 1,2,3-propanetriol, isooctadecanoate

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 and Energy.

This Public Report is 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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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	4
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION	5
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	5
BIBLIOGRAPHY	6

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1524	Reckitt Benckiser (ENA) B.V.	Decanedioic acid, polymer with 12-hydroxyoctadecanoic acid and 1,2,3-propanetriol, isooctadecanoate	No	≤ 25 tonnes per annum	Component of cosmetic products

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 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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of cosmetic 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 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.

Safety Data Sheet

The SDS of the notified polymer and products containing the notified polymer were provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Reckitt Benckiser (ENA) B.V. (ABN 52 349 643 519)
PO Box 75704 Schiphol Airport
AMSTERDAM NETHERLANDS 1118 ZT

Exempt Information (Section 75 of the Act)

Data items and details exempt from publication include: other names, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name

Decanedioic acid, polymer with 12-hydroxyoctadecanoic acid and 1,2,3-propanetriol, isooctadecanoate

Chemical Name

Decanedioic acid, polymer with 12-hydroxyoctadecanoic acid and 1,2,3-propanetriol, isooctadecanoate

CAS Number

849230-52-0

Other Name

Polyglyceryl-4 diisostearate/polyhydroxystearate/sebacate (INCI name)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 g/mol

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	Dark yellow liquid
Melting Point/Glass Transition Temperature	Liquid at room temperature
Density	980 kg/m ³ at 20 °C
Water Solubility	Not measured; insoluble; hydrophobic liquid
Dissociation Constant	Not Determined. The notified polymer contains no readily dissociable functionality.
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	≤ 25	≤ 25	≤ 25	≤ 25	≤ 25

Use

Introduction

The notified polymer will not be manufactured in Australia and will be imported in formulated finished cosmetic products in consumer containers up to 400 mL in size.

Repackaging

Imported finished cosmetic products will be repackaged locally into cardboard cartons and transported by road for distribution to retail outlets.

End Use

The notified polymer is a surfactant to be used as an emulsion stabiliser for water-in-oil creams and lotions, and other leave on and rinse off cosmetic products typically at concentrations up to 10%. The notified polymer may also be used in aerosol spray products typically at concentrations up to 5%.

The use of the notified polymer in cosmetics by the public will be widespread and repeated.

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 for the notified polymer and the analogue.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed</i>	<i>Test Guideline</i>
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity	no	OECD TG 423
Skin sensitisation – guinea pig	no evidence of sensitisation	no	OECD TG 406
Genotoxicity - bacterial reverse mutation*	non mutagenic	no	OECD TG 471

* Study conducted on the proposed analogue structurally similar to the notified polymer

All results were indicative of low hazard.

Given the low hazard, as shown above, the risk of the notified polymer to occupational and public health is not considered to be unreasonable based on the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment (Boethling & Nabholz, 1997).

The notified polymer is not manufactured or reformulated in Australia and will be imported in formulated finished cosmetic products for use on the skin in up to 400 mL in bottles, jars or tubes.

As the worst case scenario, it is assumed the majority of the notified polymer is expected to be released to the sewer as a result of its use in cosmetic products that will eventually be washed off the skin. Assuming the releases occur nationwide over the entire year and there is no removal of the notified polymer during wastewater treatment, the predicted environmental concentration (PEC) is estimated to be 14.04 µg/L [$1 \times 25,000 \text{ kg/year} \div 365 \text{ days/year} \div (24.386 \text{ million persons} \times 200 \text{ L/person/day})$]. Thus, the release of the notified polymer is not expected to lead to ecotoxicologically significant concentrations in the aquatic environment.

Empty containers containing an estimated 1% of the import volume of the notified polymer are expected to be collected and recycled or disposed of to landfill. In landfill, the notified polymer in the empty containers will be neither bioavailable nor mobile. The notified polymer is not predicted to be readily biodegradable. A study (in German) on the analogue, provided by the notifier, indicated that the analogue polymer was biodegradable but did not meet the readily biodegradable criteria. The notified polymer is also not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bio-accumulate. It is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon.

Therefore, based on its assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) Chapter 10 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, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.