

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Fatty acids, C₁₈-unsatd., dimers, di-Me esters, hydrogenated, polymers with 1-docosanol, hydrogenated C₁₈-unsatd. fatty acid dimers, isoctadecanol and soya hydroxysteroids (INCI Name: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate)

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.

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:

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**

April 2016

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.....	5
5. INTRODUCTION AND USE INFORMATION	5
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	5

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/1328	L'Oreal Australia Pty Ltd	Fatty acids, C ₁₈ -unsatd., dimers, di-Me esters, hydrogenated, polymers with 1-docosanol, hydrogenated C ₁₈ -unsatd. fatty acid dimers, isooctadecanol and soya hydroxysteroids (INCI Name: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate)	No	< 10 tonnes per annum	Cosmetic ingredient

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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a cosmetic ingredient, 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 and products containing the notified polymer were 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

L'Oreal Australia Pty Ltd (ABN: 40 004 191 673)
564 St Kilda Road
MELBOURNE VIC 3004

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: Other names, molecular and structural formulae, molecular weight, spectral data, polymer constituents, residual monomers/impurities, analogue details, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

Fatty acids, C₁₈-unsatd., dimers, di-Me esters, hydrogenated, polymers with 1-docosanol, hydrogenated C₁₈-unsatd. fatty acid dimers, isooctadecanol and soya hydroxysteroids (INCI Name: Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate)

Chemical Name

Fatty acids, C₁₈-unsatd., dimers, di-Me esters, hydrogenated, polymers with 1-docosanol, hydrogenated C₁₈-unsatd. fatty acid dimers, isooctadecanol and soya hydroxysteroids

CAS Number

654651-30-6

Other Name(s)

Bis-Behenyl/Isostearyl/Phytosteryl Dimer Dilinoleyl Dimer Dilinoleate (INCI Name)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da

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 to pale yellow hydrophobic paste
Melting Point/Glass Transition Temp	Approximately 40 °C
Density	890 kg/m ³ at 50 °C
Water Solubility	Insoluble
Dissociation Constant	Expected to be ionised under environmental conditions (pH 4–9).
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	< 10	< 10	< 10	< 10	< 10

Use

The notified polymer will be used in cosmetic products (excluding cosmetic aerosols) as a gloss, a skin and hair conditioning agent and a skin protectant.

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>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 2,000 mg/kg bw	no	OECD TG 423
2. Rabbit, skin irritation (at 100 % concentration)	non-irritating	no	OECD TG 404
3. Rabbit, eye irritation (at 100 % concentration)	slightly irritating	yes	OECD TG 405
4. Skin sensitisation – adjuvant test (Maximisation test)	no evidence of sensitisation.	no	OECD TG 406
5. Rat, oral repeat dose toxicity – 90 days (on analogue)	NOAEL of 1,000 mg/kg bw/day	no	OECD TG 408
6. Genotoxicity – bacterial reverse mutation	non mutagenic	no	OECD TG 471
7. Genotoxicity – in vitro micronucleus assay	non genotoxic	no	OECD TG 487

All results were indicative of low hazard. However, slight eye redness (score 1) was noted in all treated animals at the 1 hour observation in a Test Guideline OECD 405 eye irritation test.

The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on

alternating carbons of the polymer backbone, which does not apply to the notified polymer. The toxicity to algae is also likely to be reduced due to the presence of calcium ions in environmental waters, which will bind to the functional groups.

The notified polymer will be imported into Australia as a component of finished cosmetic formulations. The notified polymer may also be imported neat into Australia for local reformulation into a variety of personal care products and cosmetic formulations. 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 to landfill in accordance with local government regulations.

Based on its use in cosmetic formulations, 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. 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 both surface waters and landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon. 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.