File No PLC/1289

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with hydrogenated castor oil (INCI: Hydrogenated castor oil 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 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

December 2015

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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/1289	L'Oreal Australia Pty Ltd	Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with hydrogenated castor oil (INCI: Hydrogenated castor oil dimer dilinoleate)	No	< 10 tonnes per annum	Component of cosmetics

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 component of cosmetics, 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 was 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
MELBROUNE VIC 3004

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: marketing name, molecular and structural formulae, molecular weight, spectral data, purity, use details, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Chemical Name
Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with hydrogenated castor oil

CAS Number
646054-62-8

Other Name
Hydrogenated castor oil dimer dilinoleate (INCI name)

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

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	Pale yellow paste
Melting Point/Glass Transition Temp	~ 50 °C
Density	922 kg/m^3
Water Solubility	Not determined. Expected to have low water solubility based on high molecular weight and predominantly hydrophobic structure.
Dissociation Constant	Not determined. The notified polymer does not contain any functional groups that are expected to dissociate in water.
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

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

Use
The notified polymer is a binder, filler, a skin conditioning agent, hair conditioning agent, and skin protectant for use in cosmetic products.

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.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
Mouse, acute oral	LD50 > 7.5 mL/kg bw; low toxicity	no	no	Similar to OECD TG 401
Guinea pig, skin irritation – single application at 10% and 20% in liquid paraffin	non-irritating	no	no	In-house method: 8 mg of test substance applied (5 animals per dose). Evaluations conducted 3 h and 24 h after treatment.
Guinea Pig, skin irritation – repeated applications for 4 days at 10% and 20% in liquid paraffin	slight irritating	no	yes	In-house method: 8 mg test substance applied once daily for 4 days (5 animals per dose). Evaluations conducted at 24 h after each application.
Rat, skin irritation - repeated applications for 2 weeks at 10% and 25% in corn oil	non-irritating	no	no	In-house method: 0.1 mL test substance applied daily for 14 days (5 animals per dose). Evaluations conducted daily.
Rabbit, eye irritation	non-irritating	no	no	Similar to OECD TG 405
Skin sensitisation – non-adjuvant test	no evidence of sensitisation	no	no	OECD TG 406 (Buehler Method)
Skin sensitisation – adjuvant test	no evidence of sensitisation	no	no	OECD TG 406 (Maximisation Method)

All results were indicative of low hazard.

In a four day cumulative skin irritation study using 10% and 20% notified polymer in guinea pigs, the number of animals displaying irritation was observed to increase over the time period. At 10% only slight erythema was noted, whilst at 20% well-defined erythema was exhibited in 2/5 animals after the fourth application. However, a longer two week study in rats with the notified polymer at 10% and 25% in corn oil dosed daily was non-irritating. The notified polymer showed no evidence of sensitisation in guinea pig studies with and without adjuvant. The notified polymer at 100% was non-irritating to eyes.

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

The notified polymer will not be manufactured in Australia. Release to the environment may only occur in the unlikely event of an accident during transport or an accidental spill. Release of the notified polymer to the aquatic environment is not expected during local blending as any accidental spills are expected to be collected by inert material and disposed of according to local regulations. Some of the notified polymer may remain as residue in empty import containers (approximately 1% of the total annual import volume) or empty end-use containers, which is expected to be disposed of to landfill along with the empty containers.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic products. Release is assumed to occur daily, and to be diffuse in nature. Under a worst case scenario it will be assumed that 100% of the notified polymer will be washed into sewers. Assuming none of the notified polymer will be removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 6.06 µg/L [PECriver = 27.40 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC is below the EC50 for algae of the most toxic polymers (EC50 > 1 mg/L). In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it has high molecular weight.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and it is therefore not expected to bioaccumulate. The notified polymer is not readily biodegradable (1% in 28 days) and is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon.

Following use of cosmetic products containing the notified polymer, empty containers are disposed of through domestic garbage and hence will enter landfill or recycling. The residues in the empty containers are expected to account for approximately 5 % of the import volume.

Based on its assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.