File No PLC/1018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

KF-6038

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

January 2012

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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/1018	Estee Lauder Pty Ltd	KF-6038	No	≤2 tonnes per annum	Cosmetic ingredient for skin and hair conditioning

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 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.

Environmental Recommendations

- No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area.
  - Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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 being 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 MSDS of the product containing the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Estee Lauder Pty Ltd (ABN 63 008 444 719)
21 Rosebery Avenue
Rosebery NSW 2018

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, and residual monomers/impurities.

2. IDENTITY OF POLYMER

Marketing Name(s)
KF-6038

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	Not applicable
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 light brown-transparent to slightly hazy
Melting Point/Glass Transition Temp	N/A
Density	940-980 kg/m^3 at 25 °C
Water Solubility	Expected to have low solubility in water based on its predominantely hydrophobic structure
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	1	2	2	2	2

Use
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia at a concentration of 6%. Products containing the notified polymer will not be reformulated in Australia. The notified polymer will be used as a skin and hair conditioning agent, surface modifier and viscosity increasing agent in cosmetics at a concentration of 6%.

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*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 5000 mg/kg bw	no	Similar to OECD TG 401 - Limit test
Rabbit, skin irritation	slightly irritating	yes	Similar to OECD TG 404
Rabbit, eye irritation	slightly irritating	yes	Similar to OECD TG 405
Skin sensitisation	no evidence of sensitisation	no	Guinea pig skin sensitisation test (Beuhler)
Genotoxicity - bacterial reverse mutation	non-mutagenic	no	Ames mutagenicity assay

All results were indicative of low hazard.

In a skin irritation study conducted in a similar procedure to OECD TG401, intact and abraded skin of rabbits (n=6) was exposed to the notifed polymer (0.5 mL) under an occlusive patch for 24 hours and observations were taken at 24 and 72 hours after patch removal. Slight to moderate erythema was observed for all animals tested (intact and abraded sites) at the 24 hour observation period which was resolved for 5/6 of the animals at the 72 hour observation period. For the remaining animal, moderate erythema and slight oedema was still observed at both the intact and abraded sites at the end of the observation period (i.e. 72 hours). Based on these results and given no irritation was observed after treatment with the neat notified polymer in the guinea pig skin sensitisation test, the notified polymer is considered to be at most only slightly irritating to the skin.

The eye irritation potential of the notified polymer was tested in rabbits (n=3) in washed and non-washed eyes using a similar procedure to that described in OECD TG404. For both the non-washed and washed eye groups, only slight conjunctival irritation was observed at the 1 and 24 hour observation period for all animals that was completely resolved by the 48 hour observation period. The notified polymer is therefore only considered slightly irritating to the eyes.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers that have low water solubility and are without significant ionic functionality are generally of low concern to the environment.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic products that will be washed off the hair and skin. Release is assumed to occur daily, and to be diffuse in nature. A predicted environmental concentration in rivers (PEC_{river}) can be calculated on the assumption that 100% of the total annual import volume is released to sewer nationwide but that 90% of the notified polymer is removed by sewage treatment plant (STP) processes. The PEC_{river} is 0.12 µg/L if the daily chemical release (2000 kg/365 = 5.48 kg) is diluted by the daily effluent production (200 L/person/day × 22.613 million people = 4,523 ML). Therefore, the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters. The notified polymer is not

expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

The remainder of the notified polymer partitions to biosolids with an estimated concentration of 10.9 mg/kg (dry wt), and is expected to be disposed of to landfill or applied to agricultural soils for soil remediation. Up to 3% of the notified polymer may remain in residues in consumer containers and these are expected to be disposed of to landfill. When applied to agricultural soils in biosolids or disposed of to landfill, the notified polymer is expected to associate with soil and organic matter and be largely immobile based on its expected low water solubility. In landfill and soil the notified polymer may undergo soil-catalysed degradation into lower molecular weight compounds. These degradants will further oxidise, both biotically and abiotically, to form water, and oxides of carbon and silica.

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.