File No PLC/1464

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

2-Propenoic acid, octadecyl ester, homopolymer (INCI Name: Poly C10-30 Alkyl Acrylate)

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

February 2018

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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/1464	L'Oreal Australia Pty Ltd	2-Propenoic acid, octadecyl ester, homopolymer (INCI Name: Poly C10-30 Alkyl Acrylate)	No	≤ 10 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the 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 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

- Water insoluble high molecular weight polymers used in the respirable size range (< 10 μm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure.

- If aerosols are formed during the reformulation of the notified polymer, engineering controls and respiratory protection should be used to prevent inhalation exposure.

  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 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.

Safety Data Sheet

The SDSs of the notified polymer and a product containing the notified polymer were provided by the applicant. The accuracy of the information on the SDSs 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, polymer constituents, residual monomers/impurities, use details, import volume and analogue identities.

2. IDENTITY OF POLYMER

Marketing Name
Poly C10-30 Alkyl Acrylate (INCI Name)

Chemical Name
2-Propenoic acid, octadecyl ester, homopolymer

CAS Number
25986-77-0

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	White to off white pastilles
Melting Point/Glass Transition Temperature	40 – 50 °C
Density	900 – 950 kg/m^3
Water Solubility	Not determined. Expected to be low based on its predominantly hydrophobic structure.
Particle Size	Not determined. The notified polymer will be introduced in the form of solid pastilles.
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 will not be manufactured in Australia. It will be imported either as a component of formulations for reformulation into end-use cosmetics or as a component of end-use cosmetics (leave-on and rinse-off cosmetics including spray products). It may also be imported at some time in the future in the neat form as pastilles for reformulation into cosmetics within Australia. The final concentration of the notified polymer in end-use products will be < 15%.

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 two analogues.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 5,000 mg/kg bw	no	Similar to OECD TG 401 (limit test)
2. Rat, acute oral*	LD50 > 5,100 mg/kg bw	no	Similar to OECD TG 401 (limit test)
3. Rat, acute dermal*	LD50 > 2,100 mg/kg bw	no	Similar to OECD TG 402 (limit test)
4. Rabbit, skin irritation*	slightly irritating	yes	Similar to OECD TG 404
5. Rabbit, eye irritation	slightly irritating	yes	Similar to OECD TG 405
6. In vitro eye irritation – isolated calf cornea	slightly irritating	yes	In-house method: 750 mg ± 75 mg test substance applied to calf corneas for 30 minutes and then 4 hours. Optical density was measured at 490 nm.
7. Rabbit, eye irritation*	slightly irritating	yes	Similar to OECD TG 405
8. Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation	no	OECD TG 406
9. Guinea pig, skin sensitisation – non-adjuvant test*	no evidence of sensitisation	no	Similar to OECD TG 406
10. Genotoxicity – bacterial reverse mutation[#]	non mutagenic	no	OECD TG 471

* Study conducted on Analogue 1 (identity in Exempt Information)
[#] Study conducted on Analogue 2 (identity in Exempt Information)

In a skin irritation study conducted on Analogue 1, mild erythema was noted in 5 out of 6 test animals at the 1-hour observation and only in 1 animal at the 24-hour observation, which was fully resolved at the 48-hour observation.

The notified polymer when tested at 100% concentration for eye irritation in rabbits showed conjunctival effects at the 1-hour observation and corneal opacity at the 24-hour observation. All the irritation reactions resolved at the 48-hour observation.

In an *in vitro* eye irritation study conducted on Analogue 1 using isolated calf corneas, no notable opaque spots or irregularities were noted on treated corneas. The mean *in vitro* score was 1.4 following the 30-minute treatment and 1.3 following the 4-hour treatment, indicating slight irritation according to the classification criteria in the study report. In an eye irritation study conducted in rabbits, Analogue 1 was found slightly irritating to eyes. Eye irritation was limited to conjunctival irritation which was resolved in 5 out of 6 animals 72 hours after treatment and was fully resolved by Day 4.

Overall, all results were indicative of low hazard.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains impurities that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

A substantial portion of the notified polymer has a high molecular weight (> 70,000 Da) and the notified polymer is expected to have low water solubility. Inhalation of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2015). If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

Occupational Health and Safety Risk Assessment

Reformulation
In the future, the notified polymer may be imported in a solid form for local reformulation into cosmetic products. However, lung overloading effects are not expected due to the nature of the raw material (pastilles; particle size > 10 μm). Inhalation exposure to workers may occur during reformulation if aerosols are formed. Control measures including respiratory protection and local ventilation should therefore be in place to prevent inhalation exposure and hence lower the risk of potential lung overloading.

End use
Professional workers (eg. cosmetic service providers) may use spray products containing the notified polymer at < 15% concentration. The risk to such professional workers is expected to be of a similar extent to that experienced by consumers using the same products (see below).

Given the low hazard and the assessed use pattern, the risk of the notified polymer to occupational health and safety is not considered to be unreasonable.

Public Health and Safety Risk Assessment
Cosmetic products containing the notified polymer at < 15% concentration will be sold to the public. It has been proposed that the notified polymer may be used in spray products. Based on a CIR report (CIR, 2012), both pump sprays and propellant sprays (also called “aerosol sprays”) produce aerosols, but the aerosols from pump sprays have much smaller fractions of respirable droplets/particles than aerosols from propellant sprays.

Droplets/particles with d_{ae} > 10 μm may enter the nasopharyngeal region through the nose/mouth or pass through the larynx to enter the trachea, bronchi and bronchioles. In these regions of the respiratory tract, mucus-secreting and ciliated cells form a protective mucociliary blanket that carries deposited droplets/particles to the throat to be sneezed or spit out, or swallowed. There is also scientific consensus that healthy people are able to clear particles with d_{ae} > 7 μm from the nasopharyngeal and bronchial regions within 24 hours through mucociliary action (CIR, 2012).

However, droplets/particles with d_{ae} < 10 µm may reach the pulmonary region of the lung. In the pulmonary region, the clearance of water insoluble particles is mediated primarily by alveolar macrophages, and is slow and limited (CIR, 2012). Therefore, to avoid the potential for lung overloading effects, the notified polymer should not be used in spray products that are capable of generating respirable aerosols with d_{ae} < 10 µm during use. In this case, the risk to the public from use of the notified polymer at < 15% concentration in cosmetics via dermal and spray applications is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer will be imported into Australia either in end-use cosmetic products or in formulations for local reformulation into the end-use products. The reformulation processes involve blending the formulations containing the notified polymer with other ingredients in an enclosed system, followed by filling of the finished products into end-use containers. Accidental spills of the notified polymer during reformulation, transport and storage are expected to be collected for disposal in accordance with local government regulations. Any residues of the notified polymer in empty containers are expected to be disposed of by an authorised facility or washed to sewers when empty containers are rinsed with water.

The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard. This is supported by the following environmental endpoints observed in studies conducted on the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	EC50 > 100 mg/L* (nominal concentration)	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	EC50 > 100 mg/L* (nominal concentration)	Not harmful to alga up to its water solubility limit
Inhibition of Bacterial Respiration	EC50 > 1,000 mg/L (nominal concentration)	Does not inhibit bacterial activity at STPs

* > 0.52 mg/L based on measured concentration in testing medium

All ecotoxicological testing results above were indicative of low hazard.

Based on its use as a component of cosmetic products, the majority of the notified polymer is expected to be released to sewers, and then to sewage treatment plants (STPs) before potential release to surface waters. A ready biodegradability study conducted on the notified polymer shows that it is not readily biodegradable (1% degradation after 28 days). Based on its predominantly hydrophobic structure, high molecular weight and unreadily biodegradability, the majority of the notified polymer is expected to be removed through adsorption to sludge at STPs (Boethling & Nabholz, 1997; US EPA, 2013). The waste sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. A minor amount of the notified polymer may also be disposed of to landfill as collected spills and empty container residues. The notified polymer is expected to have low mobility in soil based on its predominantly hydrophobic structure. The notified polymer is not expected to bioaccumulate in biota based on its high molecular weight. In landfill, sludge and water, the notified polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water and oxides of carbon.

With 100% release of the notified polymer into the sewer systems and no removal within STPs as the worst case scenario, the predicted environmental concentration (PEC) in sewage effluent on a nationwide basis over 365 days per year is calculated to be 5.62 µg/L. A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the notified polymer is not considered to be harmful to aquatic organisms up to its water solubility limit.

The Risk Quotients (Q = PEC/PNEC) has not been calculated since the notified polymer is not considered to be harmful to aquatic organisms up to its water solubility limit. The notified polymer is not expected to be bioaccumulative due to its high molecular weight. Therefore, based on its low hazard and the assessed use pattern as a component in cosmetic products, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

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