

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Dodecanoic acid, ethenyl ester, homopolymer (INCI: Polyvinyl Laurate)

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**

September 2013

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	5
4. PHYSICAL AND CHEMICAL PROPERTIES.....	5
5. INTRODUCTION AND USE INFORMATION	5
6. HUMAN HEALTH RISK ASSESSMENT.....	5
7. ENVIRONMENTAL RISK ASSESSMENT	7

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/1141	L'Oreal Australia Pty Ltd	Dodecanoic acid, ethenyl ester, homopolymer (INCI: Polyvinyl Laurate)	No	≤ 10 tonnes per annum	Component of cosmetic products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Provided that control measures are in place to minimise worker exposure (including the use of respiratory protection by workers during reformulation activities, if ventilation is inadequate), the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

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

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed, automated processes during reformulation processes, where possible.
 - Adequate ventilation during reformulation processes and aerosol applications of products containing the notified polymer.
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer:
 - Avoid inhalation of aerosols.
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation tasks:
 - Respiratory protection, if ventilation is inadequate.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Aerosol spray products intended for professional use containing the notified polymer should carry the following safety directions (or similar) on the label:
 - Spray only in well ventilated areas.
 - Avoid inhalation of aerosol.
- 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 for the 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

- 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

- 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;
 - information on the inhalation toxicity or potential for lung overloading effects of the notified polymer becomes available;
 - the concentration of the notified polymer exceeds or is intended to exceed 15% in aerosol sprays;
 - the polymer has a number-average molecular weight of greater than 70,000 Da;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed, 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 a product 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 Rd
Melbourne VIC 3004

Exempt Information (Section 75 of the Act)

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

2. IDENTITY OF POLYMER**Marketing Name(s)**

Mexomere PP

Chemical Name

Dodecanoic acid, ethenyl ester, homopolymer

CAS Number

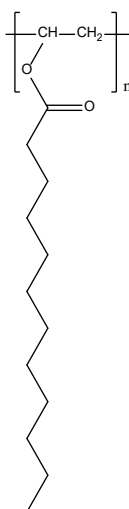
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Other Name(s)

Polyvinyl Laurate (INCI name)
Ethenyl dodecanoate, homopolymer

Molecular Formula

$(C_{14}H_{26}O_2)_x$

Structural Formula

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 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

<i>Criterion</i>	<i>Criterion met</i>
Low MW Polyester Manufactured from Allowable Reactants	Not applicable

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Cream Paste
Melting Point/Glass Transition Temp	Not determined
Density	850 kg/m ³ at 20 °C
Water Solubility	< 0.05 g/L at 23 °C. In-house methods. The solubility was evaluated by observation of the presence of little particles after the notified polymer was homogenised with water at different concentrations.
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 is a film forming ingredient, binder and viscosity increasing agent used in cosmetic products (including spray products) such as lipsticks, mascaras and foundations. The notified polymer will be imported into Australia as the raw material or as a component of finished cosmetic products. The finished cosmetic products will contain up to 15% notified polymer.

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 > 2000 mg/kg bw; low toxicity	no	OECD TG 420

2. Rat, acute dermal	LD50 > 2000 mg/kg bw; low toxicity	no	OECD TG 402
3. Rabbit, skin irritation	slightly irritating	yes	OECD TG 404
4. Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
5. Skin sensitisation – LLNA.	no evidence of sensitisation at up to 50% concentration.	no	OECD TG 429
6. Genotoxicity – bacterial reverse mutation	non mutagenic	no	OECD TG 471 – 472
7. Genotoxicity – in vitro L5178Y TK ⁺ / ⁻ mouse lymphoma cells	non genotoxic	no	OECD TG 487

All results were indicative of low hazard. Some slight skin and eye irritation was noted but was not sufficient for classification.

Toxicokinetics

The notified polymer has a high molecular weight (> 1000 Da) with a moderate proportion of low molecular weight species (< 4% with molecular weight < 1000 Da) and limited water solubility (< 1 mg/L). These characteristics are expected to limit absorption in the gastrointestinal tract, or following dermal or inhalation exposure.

Skin Irritation

In a skin irritation study conducted to OECD test guidelines the notified polymer was found to be slightly irritating to the skin of rabbits. A very slight erythema was noted in all three animals at the 1 hour observation period that resolved by the 48-hour observation period.

Eye Irritation

In an eye irritation study conducted to OECD test guidelines the notified polymer was found to be slightly irritating to the eyes of rabbits. Slight or moderate chemosis and redness of the conjunctiva were observed in all animals up to the 48-hour observation period. Slight chemosis and redness of the conjunctiva persisted until Day 4 and on Day 3, respectively, in one of them. An iris lesion was noted in 1/3 animals on Day 1 only.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

The notified polymer is a high molecular weight (10,000-70,000 Da) polymer with low water solubility. Inhalation of respirable particles 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, 2013). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity, is uncertain.

Occupational Health and Safety Risk Assessment

The primary risk to human health from use of the notified polymer will be due to the potential for lung overloading effects following repeated inhalation exposure. The notified polymer in the neat form is a paste therefore inhalation exposure is only expected where aerosols may be formed.

Reformulation

Although reformulation workers will handle the imported notified polymer frequently at concentrations of $\leq 100\%$, exposure is expected to be minimised given the proposed use of PPE and largely enclosed, automated processes used in reformulation facilities. The risk to the health of reformulation workers is therefore not considered to be unreasonable, provided control measures are in place to minimise worker exposure (including the use of respiratory protection if ventilation is inadequate).

End users

The notified polymer is intended to be used in a range of cosmetics products at $\leq 15\%$ concentration. The risk to workers who regularly use non-aerosol spray products containing the notified polymer is expected to be of a similar or lesser extent than that experienced by members of the public who use such products on a regular basis. For details see public health risk assessment.

Regarding use in aerosol spray products, based on the high molecular weight and low water solubility of the notified polymer, the potential for lung overloading effects from repeated inhalation exposure to the notified polymer cannot be ruled out, particularly where there is high and/or frequent exposure. Thus the potential for lung overloading effects may be of specific concern to professional workers such as hairdressers who regularly use spray products containing the notified polymer, although the degree of exposure is likely to vary greatly depending on the amount and frequency of application and the spray environment (e.g. room size and degree of ventilation).

Therefore, provided exposure of workers to aerosol hair sprays is limited through the use of control measures (e.g. users directed to only apply hair sprays in well ventilated areas and to avoid inhalation of the spray contents), the risk to the health of workers is not considered to be unreasonable.

Public Health and Safety Risk Assessment

The general public will have widespread and repeated exposure to cosmetic products containing the notified polymer at $\leq 15\%$ concentration. Local and systemic toxicity effects following dermal exposure to the notified polymer are not expected. However, as noted above, the greatest concern associated with use of products containing the notified polymer, is the potential for lung overloading effects following inhalation exposure.

Regarding use in aerosol spray products (e.g. hair spray), the frequency of exposure of members of the public to the notified polymer is expected to be less than that of professional workers such as hairdressers (considered to represent a worst case scenario). Overall, it is assumed that if the notified polymer is inhaled at low levels and/or infrequently, that it will be cleared from the lungs.

Therefore, under the proposed use scenario, the risk to the health of members of the public is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

Release of the notified polymer to the aquatic environment is not expected during reformulation as residues in equipment washings and import containers (1% of the total import volume) are expected to be collected and disposed of according to local regulations. Some of the notified polymer (3%) may remain in residues in 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 personal care and cosmetic products that will be washed off 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 assumptions that 100% of the total annual import volume is released to sewer nationwide with 90% removal of the notified polymer by sewage treatment plant (STP) processes (Boethling and Nabholz, 1997). The PEC_{river} is calculated to be 0.61 $\mu\text{g/L}$ if the daily chemical release 2.74 kg ($= 10\% \times 10000 \text{ kg} \div 365$) is diluted by the daily effluent production 4,523 ML ($= 200 \text{ L/person/day} \times 22.613 \text{ million people}$). The PEC indicates the release of the notified polymer will not reach ecotoxicologically significant concentrations. Notified polymer partitioning to biosolids with an estimated concentration of 54.52 mg/kg (dry wt) is expected to be disposed of to landfill or applied to agricultural soils for soil remediation.

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. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. The notified polymer is expected to eventually degrade 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.

BIBLIOGRAPHY

Boethling RS & Nabholz JV (1997) 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. New York, Van Nostrand Reinhold, pp 187–234.

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