

File No PLC/946

September 2010

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

FULL PUBLIC REPORT

HDI/Trimethylol Hexyllactone Crosspolymer

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the 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 Department of the Environment, Water, Heritage and the Arts.

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

This Full 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:

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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES.....	4
5. INTRODUCTION AND USE INFORMATION.....	4
6. HUMAN HEALTH IMPLICATIONS	4
7. ENVIRONMENTAL IMPLICATIONS	6
8. CONCLUSIONS AND RECOMMENDATIONS	6

FULL PUBLIC REPORT**HDI/Trimethylol Hexyllactone Crosspolymer****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

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

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Import Volume, Percentage of notified polymer used in finished imported products, and Site of Manufacture/Reformulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Water solubility and charge density.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

HDI/Trimethylol Hexyllactone Crosspolymer

MOLECULAR WEIGHT (MW)

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

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION*Criterion*

Molecular Weight Requirements
Functional Group Equivalent Weight (FGEW) Requirements
Low Charge Density
Approved Elements Only
Stable Under Normal Conditions of Use
Not Water Absorbing
Not a Hazard Substance or Dangerous Good

Criterion met

Yes
Yes
Yes
Yes
Yes
Yes
Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Fine white to pale yellow powder
Melting Point/Glass Transition Temp	>225°C
Density	1100-1250 kg/m ³ at 20°C
Water Solubility	Not determined. The notified polymer is expected to be insoluble in water, based on its high molecular weight and largely hydrophobic, cross-linked structure.
Dissociation Constant	Not determined. The notified polymer has no dissociable functions.
Particle Size	The particle size of the two grades of the notified polymer were determined using a Coulter Counter: Grade 1: <100 µm = 100% <10 µm = 33.8% <1 µm = 5.5% Diameter at 50% = 12.54 µm Grade 2: <100 µm = 100% <10 µm = 87.5% <1 µm = 7.1% Diameter at 50% = 6.16 µm
Reactivity	Stable under normal conditions of use. Airborne polymer dust may form explosions under conditions of poor ventilation.
Degradation Products	None under normal conditions of use. Carbon oxides, nitrogen oxides, hydrogen cyanide, isocyanates and amines may be formed upon thermal decomposition.

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	1	1	1	1	1

Use

The notified polymer, in the form of silica-coated “microspheres”, will be used at up to 20% concentration in a range of cosmetic products to improve the anti-caking and “skin feel” of cosmetic products. These microspheres induce light scattering and imparts a “soft-focus” effect to applied cosmetics, and absorb limited amounts of oil from the skin surface.

Mode of Introduction

The notified polymer will not be manufactured or reformulated in Australia and will be imported as a component of finished cosmetic products at up to 20% concentration.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer (Grade 1).

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	
Rat, acute oral	LD ₅₀ >5000 mg/kg bw	no	Non-standard test method
Rabbit, skin irritation	Slightly irritating	yes	Non-standard test method
Human, skin irritation patch test	Non-irritating	no	No standard test method available
Rabbit, eye irritation	Slightly irritating	yes	Non-standard test method

All toxicological study results were supportive of the assumption of low hazard.

An acute oral toxicity study in a group of 5 males and 5 females Wistar-strain rats was carried out, using a dose level of 5000 mg/kg bw administered by intra-gastric feeding. Animals were observed for signs of pharmacologic activity and drug toxicity at 1, 3, 6, and 24 hours then at least once daily for 14 days. No symptoms or mortality was observed.

Slight irritation of rabbit skin was observed in 5 of 6 animals in the primary dermal irritation study, after application as 100% concentration of the notified polymer to either intact or abraded skin. One animal showed well-defined erythema and slight oedema at 24 and 72 hours after application. The irritation scores were not sufficient to warrant classification of the notified polymer according to Approved Criteria (NOHSC, 2004).

A non-GLP study to investigate the irritation and sensitisation effect by the human skin patch tests using 44 human volunteers (21M/23F) exposed to a dry powder of the notified polymer for 48 hours, showed no effects. This study may not be predictive of effects within moist formulations.

In the eye irritation study, mild to moderate conjunctival redness and mild chemosis were observed with 100% notified polymer at 24 and 48 hours after instillation in 4 of 6 rabbits, and one rabbit showed redness after 4 days. This had disappeared by 7 days. One animal showed mild chemosis on day 1, but this had disappeared by day 2. Therefore, the notified polymer was considered to be slightly irritating to eyes, but the scores were not sufficient (the mean scores of the 24, 48 and 72 hour observations were 1.0 for redness and 0.1 for chemosis) to warrant classification according to Approved Criteria (NOHSC, 2004). Due to the particle size and the water insolubility of the notified polymer, the eye irritation observed was likely due to mechanical abrasion rather than chemical irritancy.

The ability of the notified polymer to cause skin sensitisation has not been experimentally determined. However, given the high molecular weight of the notified polymer (>10000 Da) and its low content of low molecular weight species, significant dermal absorption is not expected to occur to lead to sensitisation.

Both grades of microspheres of the notified polymer contain particles of respirable size (<10 µm). Respirable, high molecular weight, insoluble polymer particles are considered to be of some concern, due to studies in which irreversible lung damage was linked with inhalation of respirable particles of water-insoluble polymers (US EPA (2007) *High Molecular Weight Polymers in the New Chemicals Program*). This is expected to be a physical effect; i.e. deposition of particles to the deep lung from where they cannot be removed by normal clearance mechanisms. This may lead to lung overloading at higher exposure levels. Normal lung clearance mechanisms are expected to tolerate low exposures to the notified polymer.

Occupational Health and Safety Risk Assessment

Occupational exposure to the notified polymer before end use will be unlikely except in the event of accidental spills or leakage during transport or retail handling. Therefore, the risk to such workers is considered to be low due to the assumed low hazard of the notified polymer and the negligible exposure.

Intermittent, wide-dispersive use with direct handling may occur among hairdressers, cosmeticians, and beauticians that may apply the imported cosmetic products containing the notified polymer. Frequent dermal and occasional ocular exposure to the notified polymer (at up to 20%) is probable, but given the assumed low hazard of the notified polymer, and that it is only slightly irritating and present at low concentrations, this is unlikely to result in significant risk to these workers.

Although airborne particles of the notified polymer may be generated during the use of “dry” cosmetics (e.g. face powders), inhalation exposure levels are not expected to be high due to the infrequent nature of applications. In addition, the finished cosmetic products are comprised of many components (e.g. binders, pigments, etc.) that will bind to particulates of the notified polymer and increase their effective particle size, such that inhalation to the deep lung would be less likely. The Australian recommended exposure standard for nuisance dust is 10 mg/m³ [NOHSC 3008:(1995)].

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the assumed low hazard of the notified polymer.

Public Health Risk Assessment

Public exposure to the notified polymer will be widespread and will vary depending on individual use patterns and the type of cosmetic product applied. Exposure is expected to be primarily dermal, although ocular, ingestion and inhalation exposure are also likely to occur. Significant absorption of the notified polymer is not expected to occur following ingestion or through the skin, due to its very high molecular weight, insolubility

and particle size.

The potential risks to public health are not considered to be significant due to its assumed low hazard (also proven by same test data. Ocular exposure may present some risk of mild, transient irritation due to mechanical abrasion.

Inhalation exposure to high levels of particulates of the notified polymer might present a potential risk of lung effects (described above). However, inhalation exposure levels of the notified polymer are likely to be limited by the small scale of cosmetic product application and by the effect of cosmetic product ingredients on the generation of inhalable or respirable particulates. The application of “dry powder” cosmetic products that might contain the notified polymer would present the highest level of risk in this regard, but as exposures are likely to be for very low volumes, of short duration and infrequent, this risk is not expected to be unacceptable.

Overall, the notified polymer is not expected to pose an unacceptable risk to public health from its use in formulated cosmetic products.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data for the notified polymer were submitted. Ecotoxicological data were provided for a similar polymer to the notified polymer. However, the similar polymer was not considered to be a suitable analogue to the notified polymer and the ecotoxicological test results were not considered in this assessment. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Risk Assessment

The majority of the notified polymer will be released to the aquatic compartment, via discharge of cosmetic products containing the notified polymer into sewers through bathing. Release is assumed to occur daily, and to be diffuse in nature. Of the maximum importation volume, 97% is expected to be discharged to the sewer, while the remainder will remain in product containers as residues and be disposed of to landfill.

Significant hydrolysis is unlikely to occur in the environmental pH range of 4–9. Non-ionic polymers with a molecular weight > 1000 Da are assumed to partition mainly to solids. The polymer is not expected to cross biological membranes due to its high molecular weight and as such should not bioaccumulate.

Any notified polymer that is disposed of to landfill is expected to associate with soil and organic matter and be largely immobile. Over time, the notified polymer will eventually degrade via biotic and abiotic processes to form oxides of carbon and nitrogen.

A predicted environmental concentration (PEC) for a worst case scenario can be calculated on the assumptions that 100% of the total annual import volume is released daily to sewer nationwide, and that none of the notified polymer is removed by sewage treatment plant (STP) processes. The PEC_{river} is 0.647 µg/L if the chemical release ($1000 \text{ kg}/365 = 2.74 \text{ kg}$) is diluted by the daily effluent production ($200 \text{ L/person/day} \times 21.16 \text{ million people} = 4,232 \text{ ML}$). As no suitable ecotoxicity data are available, a predicted no effect concentration (PNEC) for the aquatic compartment and Risk Quotient (Q) were not determined. However, given the expected low ecotoxicity of the notified polymer together with the expected diffuse release pattern (contributing to low environmental concentrations), the environmental risk is not expected to be unacceptable.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

When used as a cosmetic product ingredient (at concentrations of <20%), the notified polymer is not considered to pose an unacceptable risk to the health of workers or to members of the public.

Environmental risk assessment

Based on the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

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 chemical 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 chemical 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.
 - the notified polymer is imported in any fashion other than as a component of finished cosmetic products.
 - the notified polymer is imported with particle sizes lower than 0.3 µm.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of finished cosmetic products, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from one tonne, or is likely to increase, significantly;
 - if 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 notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.