

File No PLC/763

February 2008

**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 334-336 Illawarra Road, Marrickville NSW 2204.

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:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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.....	3
5. INTRODUCTION AND USE INFORMATION.....	4
6. HUMAN HEALTH IMPLICATIONS	4
Hazard Characterisation.....	4
7. ENVIRONMENTAL IMPLICATIONS	6
Hazard Characterisation.....	6
8. CONCLUSIONS AND RECOMMENDATIONS.....	6
Human health risk assessment	6
Recommendations.....	6
Regulatory Obligations	7

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

APPLICANT(S)

Avon Products Pty Ltd (ABN 48 008 428 457) of 120 Old Pittwater Rd, Brookvale, NSW 2100

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, Use Details, Import Volume and Identity of Manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

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)	>10000 Da
% of Low MW Species < 1000 Da	<1%
% of Low MW Species < 500 Da	<1%

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

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

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Fine white powder
Melting Point	>225°C
Density	1100-1250 kg/m ³ at 20°C
Water Solubility	No solubility test was provided. It is expected to be insoluble in water,

	based on its high molecular weight and largely hydrophobic, cross-linked structure.
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>
<i>Tonnes</i>	1	1	1	1	1

USE

The notified polymer, in the form of silica-coated “microspheres”, will be used as a <20% component of 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.

The notified polymer-containing cosmetic products will be sold to the public for topical cosmetic applications.

MODE OF INTRODUCTION AND DISPOSAL

The notified polymer will be imported from China into Port Botany, Sydney, within finished cosmetic products. These products will not be repackaged, but will be warehoused before being sold to members of the public.

The majority of the imported volume of notified polymer will eventually be released into the environment (up to 970 kg) via discharge into sewerage systems through bathing. Disposal will take place in domestic bathrooms or similar ‘wet’ areas that normally drain to sewerage. It is expected that up to 3% (30 kg per annum) will remain in the consumer product containers and will be disposed of to landfill.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and therefore is assumed to be of low hazard. This assumption is supported by toxicological endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</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.

Slight irritation of rabbit skin was observed in 5 of 6 animals in the in the primary dermal irritation study, after application to either intact or abraded skin. One animal showed well-defined erythema and slight oedema 24 and 72 hours after application. The level of irritation observed was not sufficient to warrant classification of the notified polymer according to NOHSC*. A non-GLP study 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 at 24 and 48 hours after instillation in 4 of 6 rabbits, and while one rabbit still 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 to warrant classification according to NOHSC* (the mean scores of the 24, 48 and 72 hour observations were 1.0 for redness and 0.1 for chemosis). 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, calculated) 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**. 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.

* NOHSC *Approved Criteria For Classifying Hazardous Substances* [NOHSC:1008(2004)].

** US EPA (2007) *High Molecular Weight Polymers in the New Chemicals Program*
(<http://www.epa.gov/oppt/newchemicals/pubs/hmwtpoly.htm>)

Occupational Health and Safety Risk Assessment

Occupational exposure to the notified polymer before end use will be unlikely except in the event of 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 <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 American Conference of Governmental Industrial Hygienists (ACGIH) recommends an exposure standard of 3 mg/m³ for “respirable particulates (insoluble), not otherwise regulated”, which would apply to the notified polymer.

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 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 and tested low hazard, and because of the low concentrations present in finished cosmetic products (<20%). 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 small, 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 (<20% concentration).

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. 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 into sewers through bathing. Release is assumed to occur year-round, and to be diffuse in nature. Of the maximum importation volume of 1000 kg, the majority (97%, or 970 kg) is expected to be discharged to sewage, while the remainder (3%, or 30 kg) would remain in product containers, to be disposed of into landfill.

The notified polymer contains functionality that may hydrolyse under extreme pH. However, significant hydrolysis is unlikely to occur in the environmental pH range of 4-9. Non-ionic polymers with an Mn >1000 Da are assumed to partition mainly to solids. However, the notifier states that 70% of the polymer may potentially remain in suspension (possibly associated with the use of surfactants in the cosmetic product). The polymer is not expected to cross biological membranes due to its high molecular weight (Mn >10000 Da, based on theoretical calculation), 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 should eventually degrade via biotic and abiotic processes to form simple organic and nitrogen-based compounds. Degradation products (also including products from thermal degradation) include oxides of carbon and nitrogen, hydrogen cyanide, isocyanates and amines.

An inland predicted environmental concentration (PEC) of 0.66 µg/L for suspended notified polymer is calculated for a worst case scenario, but this is reduced to 0.46 µg/L based on the notifier's assumption that 70% of the notified polymer remains in suspension. As no ecotoxicity data are available, a predicted no effect concentration (PNEC) for the aquatic compartment and resultant Risk Quotient (Q) are unable to be determined. However, given the likely low ecotoxicity 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

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

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.

Environment

- The notified polymer should be disposed of by landfill.
- Large spills and/or accidental releases of the notified polymer should be handled by the use of absorbants (sand, vermiculite or earth). Spills should be prevented from entering drains or watercourses.

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 (notified polymer concentration <20%).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.