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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Panalene® H-300E

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Panalene® H-300E****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Amway of Australia
46 Carrington Road
CASTLE HILL NSW 2154

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

- Chemical identification
- Molecular weight

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Notified polymer has been notified in the EU.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Panalene H-300E

PLC CRITERIA JUSTIFICATION

Insert more rows for FGs if required

Molecular Weight	The notified polymer satisfies the molecular weight criteria
Reactive Functional Groups	The notified polymer has no groups of high or moderate concern
Charge Density	The notified polymer has low charge density.
Elemental Criteria	The notified polymer contains only approved elements.
Degradability	The notified polymer is not biodegradable.
Water Absorbing	The notified polymer is not a water-absorbing polymer.
Residual Monomers	All residual monomers are below the relevant cut-off.
Hazard Category	The notified polymer is not classified as a hazardous substance.

The notified polymer meets the PLC criteria.

4. 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>Kilograms</i>	40	40	40	40	40

USE

The notified polymer is intended for use as an emollient in an artistry glossy lip shine product. The notified polymer will not be manufactured or reformulated in Australia. The notified polymer will be imported in a finished lip-gloss product at a concentration of 88-97%. The product is packaged in 9 mL containers that are then over-packaged in cartons for transport and storage.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Clear thick viscous liquid
Melting Point/Glass Transition Temp	Not applicable - liquid
Density	0.885 kg/m ³ (test temperature not provided)
Water Solubility	Not determined However, the MSDS supplied in the submission suggests that the notified polymer's water solubility is less than 1000 mg/L. Furthermore, given its fully hydrocarbon structure it is not expected have any appreciable solubility in water.
Particle Size	Not applicable - liquid
Degradation Products	None expected
Loss of monomers, other reactants, additives impurities	None expected

OTHER PROPERTIES

Hydrolysis as a Function of pH	The notified polymer does not contain any linkages that could be expected to undergo hydrolysis in the environmental pH range of 4 to 9.
Partition Coefficient (n-octanol/water)	The notified polymer's low expected water solubility and likely hydrophobic nature are indicative of partitioning into the octanol phase.
Adsorption/Desorption	The notified polymer is expected to have a high affinity for soil and sediment and be immobile in the environment due to its low expected water solubility.
Dissociation Constant	The notified polymer does not contain any groups that are expected to dissociate in the environmental pH range of 4 to 9.

7. HUMAN HEALTH IMPLICATIONS

7.1 Toxicology

Toxicological Investigations

No toxicological data were submitted for the notified polymer, however the MSDS provides the following toxicological data for a surrogate chemical:

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50	> 34 600 mg/kg
Rat, acute dermal LD50	> 10 250 mg/kg
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	non-irritating

The MSDS also states that in a two year rat and dog study and a three-generation reproduction study, similar materials caused no adverse effects when fed at levels as high as 2% in the diet.

Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

7.2 Occupational Health

Occupational Exposure

Manufacture or reformulation of the notified polymer will not take place in Australia. Workers involved in the transport and storage of the products containing the notified chemical may only be exposed to the notified polymer in the event of an accident where the packaging of the lip gloss product may be breached.

Exposure Assessment

During transport and storage, workers are unlikely to be exposed to the notified polymer due to the degree of packaging, the small amount of the notified polymer per container, and the physical characteristics of the product.

7.3 Public Health

Public Exposure

Due to the intended cosmetic use of the product, some members of the public may be exposed to the notified polymer *via* direct application. Based on the import volume and the concentration of the notified polymer in the product, it is expected that approximately 5000 units of the lip-gloss products will be available to the public every year.

Exposure Assessment

Cosmetic products containing the notified polymer are for sale to the general public. Members of the public will make dermal contact through application of the product and possibly accidental ocular contact with products containing the notified polymer. As the product is applied to the lips, a degree of oral ingestion may also be expected. Approximately 0.01 g of product is expected to be applied 2-6 times per day by the consumer (EC, 1996), giving a maximum exposure to approximately 0.06 g of notified polymer per day.

8. ENVIRONMENTAL IMPLICATIONS

8.1 Ecotoxicology

Ecotoxicological Investigations

The surrogate ecotoxicity data (see below) indicated in the MSDS provided as part of the submission suggests that the notified polymer is likely to be non-toxic to fish, daphnia and microorganisms.

Species	Result
Fish – 96 h	
Trout	LC50 > 10000 mg/L
Minnow	LC50 > 1000 mg/L
Daphnia – 48 h	EC50 > 10000 mg/L
	EC50* > 1000 mg/L

* Water-Soluble Fraction (WSF)

Most acute toxicity studies were conducted with the water accommodated fraction (WAF). The inhibition of bacterial activity by the notified polymer was assessed using a modified OECD TG 209 method. The test found that activated sludge microbes were not inhibited at test substance loading of up to 25 mg/L.

8.2 Environmental Contamination

Environmental Exposure

The majority of the notified polymer will eventually be released into the environment through discharged into the sewer. Residual polymer within empty containers or with residual solids derived from water treatment at sewage treatment facilities will be disposed of to landfill.

Data regarding the bioaccumulation potential of the notified polymer were not provided. The chemical structure, water solubility, and Pow suggest a potential for the notified polymer to cross biological membranes and bioaccumulate (Connell 1990). However, the notified polymer's high molecular weight (>1000) would suggest the potential for bioaccumulation is low.

Exposure Assessment

The notified polymer is not expected to be soluble in water and as such is unlikely to be mobile in either aquatic or terrestrial compartments. When released to sewer and landfill, as a consequence of its low water solubility, the notified polymer is expected to associate with soil and sediment and be slowly degraded through the abiotic and biotic processes to water and oxides of carbon. Incineration of the notified polymer will produce water and oxides of carbon.

9. RISK ASSESSMENT

9.1. Environment

The notified polymer will be used in cosmetics and, as such, this will result in the eventual release of almost the entire import volume to the environment from use. However, as a consequence of its expected low water solubility, the notified polymer is likely to associate with soil and sediment and degraded through the abiotic and biotic processes to water and oxides of carbon.

Based on annual imports of 40 kg per annum, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 0.11 kg/day. Assuming a national population of 19 500 000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentrations in sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer annually	40 kg
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365

Estimated PEC _{aquatic} (Ocean)	0.003 µg/L
Estimated PEC _{aquatic} (River)	0.028 µg/L

The most sensitive species are fish and daphnia with 96 h LC50 and 48 h EC50 values of greater than 1000 mg/L. Using a worst case scenario safety factor of 100, the predicted no effect concentration (PNEC) is greater than 10 mg/L. The worst-case PEC/PNEC ratios for the aquatic environment if the notified polymer is used nation wide when released to ocean and inland river are 0.0003 and 0.0028, respectively. These values are significantly less than 1, indicating no immediate concern to the aquatic compartment.

Furthermore, given the notified polymer's expected low water solubility, its removal from the wastewater stream is expected to be high.

The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

9.2 Occupational health and safety

The notified polymer meets the PLC and can therefore be considered of low hazard. Additionally, surrogate data for similar chemicals support the low hazard claims. The OHS risk presented by the notified polymer is therefore expected to be low, given the lack of opportunity for worker exposure and the low hazard associated with the polymer.

9.3 Public health

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is no concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is negligible concern to public health when used in the intended manner.

11. 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of

State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- Wastes containing the notified polymer should be disposed of to landfill or be incinerated.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie. collect spilled material) and the resulting waste incinerated.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Connell DW (1990). Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

European Commission (1996). Technical Guidance Document in Support of Commission Directive. 93/67/EEC on Risk Assessment of New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances. Parts I-IV. Office of Official Publications of the European Communities, 1996.

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.