File No PLC/398

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylates/Palmeth-25 Acrylate Co-polymer

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 and Heritage.

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Director
Chemicals Notification and Assessment

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Acrylates/Palmeth-25 Acrylate Co-polymer

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Unilever Australia Pty Ltd
219 North Rocks Road
NORTH ROCKS NSW 2151

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- Other names
- CAS number
- Molecular formula
- Structural formula
- Polymer constituents
- Manufacturer

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Particle size distribution
- Autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Evaluated in US by CIR panel.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Acrylates/Palmeth-25 Acrylate Co-polymer

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	4.7	0	0	0	0

USE
The notified polymer will be used as a viscosity modifier in finished cosmetic shower gels.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description
The notified polymer will be imported as a component of finished cosmetic shower gels at a concentration of 2.7-3%. Consumer products will be imported and transported to retail outlets for sale.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure
The notified polymer will be incorporated into shower gels and released to the environment during washing. Approximately 1% of the product may remain in the empty import containers, equating to less than 47 kg of notified polymer.

The shower gel will be washed down the drain, thus releasing the majority of the notified polymer to sewer. The end-user container containing any residual material will be disposed into general rubbish, which goes to landfill. While the notified polymer contains groups which are potentially hydrolysable, this is not expected to occur in the environmental pH range of 4-9. In sediment/landfill it may be anticipated that the polymer will slowly degrade.

The notified polymer is not expected to be very soluble in water and as such is expected to be relatively immobile in either the aquatic or terrestrial compartments. Residual chemical disposed of into landfill within empty containers or in spill clean-up material, is not expected to leach from landfill.

6.2. Summary of Occupational Exposure
Transport & Storage
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 polymer may only be exposed to the notified polymer in the event of an accident where the packaging consumer product may be breached. In these circumstances exposure to will be limited to contact with consumer products containing a maximum of 3% notified polymer.

Retail
Retail workers involved in the shelf filling and sale of the final consumer product are not expected to be exposed to the notified polymer except in cases of an accident where the packaging may be breached

End-Use
Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE (1997) modelling of this work environment, exposure in the range of 1-5mg/cm^2.day of products containing up to 3% of the notified polymer could result. Dermal exposure is expected during application of certain products and accidental ocular exposure may also occur. The notified polymer is non-volatile, however, if it is present in product applied as a mist or aerosol, inadvertent inhalation of the notified polymer may also occur.

6.3. Summary of Public Exposure
Cosmetic products containing the notified polymer at concentrations of up to 3% are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. In most cases exposure is expected to be limited to 1-10

grams of product, 1-2 times per day.

7. PHYSICAL AND CHEMICAL PROPERTIES

The physicochemical data available for the notified polymer are for its 30-32% aqueous emulsion.

Appearance at 20ºC and 101.3 kPa	White opaque emulsion in water
Melting Point/Glass Transition Temp	<10ºC
Density	1000 kg/m^3
Water Solubility	Stated to be insoluble in water. No data are available but the presence of acidic and ether functionalities have the potential to increase solubility.
Dissociation Constant	Information not supplied. The notified polymer contains functional groups that could be expected to dissociate under most of the environmental range (pH 4-9).
Particle Size	Not applicable. Notified polymer is always in solution.
Reactivity	Stable under normal environmental conditions.
Degradation Products	None expected.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

No toxicological data were submitted.

8.2. Human Health Hazard Assessment

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

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

As no data are available it is not possible to characterise aquatic toxicity. However, due to its very large molecular weight and low water solubility, the polymer is expected to be of low concern to aquatic organisms. In addition, polynonionic polymers which have a MW > 1000 are regarded as low concern.

10. RISK ASSESSMENT

10.1. Environment

Based on the import of 4,700 kg per annum of the notified polymer, and assuming the majority of this is eventually released to sewer and not removed during sewage treatment processes, the following Predicted Environmental Concentration can be estimated

Amount of notified polymer entering sewer annually	4 700 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365

PEC_{sewer} $\frac{4\ 700\ 000\ 000 \text{ mg}}{20\ 000\ 000 \times 200 \times 365 \text{ L}}$
= 0.0032 mg/L
= 3.2 µg/L

When released to receiving waters (ocean) the concentration is generally understood to be reduced by a further factor of at least 10. However, as the shower gel products containing the notified polymer will be used nationwide, no further dilution on release to receiving waters will be assumed as a worst-case estimate.

Since no ecotoxicological data were provided, a hazard quotient (HQ = PEC/PNEC) cannot be calculated. However, based on the proposed use pattern of the notified polymer, the amount being imported, the nationwide use of the shower gel products and subsequent diffuse release and its expected low toxicity it is not expected to pose an unacceptable risk to aquatic life.

It is unlikely that the new polymer will present a hazard to the environment when handled and used as indicated. Hence, environmental risk from the proposed use is expected to be low.

10.2. Occupational health and safety

The greatest potential for occupational exposure occurs in those professions, such as hairdressing and beauty therapy, where workers may apply the product containing the notified polymer several times each working day. Dermal exposure is the main route of exposure although inadvertent ocular exposure may also occur. The notified polymer is of low hazard, high molecular weight, and present at low concentrations, therefore the risk to these workers is considered low.
The OHS risk presented by the notified polymer during transport, storage, and reformulation is also expected to be low due to its expected low hazard and low potential for worker exposure.

10.3. Public health

The products containing the notified polymer will be used by the general public applying the products themselves, and also by those having products applied during professional hairdressing or cosmetic applications. The notified polymer has a NAMW > 1000, and thus will be unable to cross biological membranes. Despite the potential widespread use, the risk to public health is considered low due to the non-hazardous nature of the notified polymer.

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

11.1. Environmental risk assessment

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

11.2. Human health risk assessment

11.2.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2 Public health

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

12. MATERIAL SAFETY DATA SHEET

Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. 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

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
  - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified polymer should be disposed of by landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment with absorbent material, collection and storage in sealable labelled container.

13.1. 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.