

File No PLC/791

19 August 2008

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

FULL PUBLIC REPORT

Polymer in Aculyn 88

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**

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FULL PUBLIC REPORT**Polymer in Aculyn 88****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Rohm and Hass Australia Pty. Ltd. (ABN 29 04 513 188)
4th Floor, 969 Burke Road
Camberwell VIC 3124

Colgate-Palmolive Pty Ltd (ABN 79 002 792 163)
345 George St
Sydney NSW 2000

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities.

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

None known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Aculyn 88

INCI name: Acrylates/Steareth-20 Methacrylate Crosspolymer

CAS NUMBER

Not assigned

OTHER NAME(S)

None known

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

<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:	Clear colourless solid. The notified polymer will be imported in an aqueous emulsion from which it will not be isolated.
Melting Point/Glass Transition Temp	Not determined. The notified polymer will be imported in an aqueous emulsion from which it will not be isolated.
Density	1000 to 1100 kg/m ³ at 25°C for the notified polymer as a 25% w/w emulsion in water.
Water Solubility	254 mg/L in water and 112, 229 and 234 mg/L at pH 2, 7 and 9 respectively, which is consistent with the polyanionic structure.
Dissociation Constant	Not determined. The notified polymer contains carboxylic acid functionality and is expected to have typical acidity (pKa 3-5).
Particle Size	Not determined. The notified polymer will be imported in an aqueous emulsion from which it will not be isolated.
Reactivity	Stable under normal environmental conditions. While the notified polymer contains hydrolysable functionality, the results of abiotic degradation (hydrolysis) testing submitted indicate that this will not occur within the environmental pH range of 4-9.
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	2	3	4	5	6

Use

The notified polymer will be used as a thickener, stabilizer and suspending agent in the manufacture of shampoo, body wash, face wash and other personal care products.

The notified polymer will be used at a concentration up to 3% in personal care products.

Mode of Introduction and Disposal

The notified polymer will not be manufactured in Australia.

The notified polymer will be imported by sea through the ports of Melbourne or Sydney as a 25% w/w aqueous emulsion (Aculyn 88) and as a component of personal care products at concentrations up to 1.5% w/w. The Aculyn 88 product will be imported in 200 L plastic drums, while the personal care products will be imported in plastic containers generally ranging in size from 100 mL to 1 L.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Occupational Health and Safety Risk Assessment

Reformulation

Dermal and ocular exposure can occur during weighing out prior to reformulation and during filling line operation, cleaning and maintenance. However exposure to significant amounts of the notified polymer will be limited by the use of personal protective equipment, including impermeable gloves, eye protection and coveralls.

End use

Exposure of beauticians and hairdressers to the notified polymer at concentrations of $\leq 3\%$ w/w could occur during final application of the cosmetic products to their clients. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. PPE is not expected to be worn, however good hygiene practices are expected to be in place.

Although exposure to the notified polymer could occur during reformulation and end use, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

Public Health Risk Assessment

The general public will be repeatedly exposed to the notified polymer at concentrations up to 3% w/w, via a number of different consumer products. Exposure to the notified polymer will vary depending on individual use patterns.

Although the public will be exposed to the notified polymer during use of personal care products, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. Generally, this type of polyanionic polymer will not be toxic to fish or daphnids, with a $LC_{50} > 100$ mg/L. However, anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The most toxic form is when the acid is on alternating carbons of the polymer backbone, with the 96 h EC_{50} for green algae ranging from 3.13 to 37.4 mg/L with a geometric mean of 8.6 mg/L. Thus, with a conservative assessment factor of 1000, the resultant Predicted No Effect Concentration (PNEC) is 8.6 μ g/L.

Environmental Risk Assessment

Release to the environment during shipping, transport and warehousing should only occur through accidental spills or leaks of the drums or steel packaged containers.

During reformulation and packaging, spills are expected to be minimal. When spills occur, they are expected to be physically contained by bunding, collected with absorbent material and be sent to a licensed off-site waste disposal facility. Empty drums from import will be sent to drum reconditioners, where any residual notified polymer is expected to be removed and be disposed of to landfill, or where permissible, by incineration.

Cleaning of reformulation and packaging equipment will be performed by flushing with water. Typically, cleaning water and product residues will be transferred to the on-site waste treatment facility where solids will be precipitated and later disposed of to a licensed waste landfill site.

The total amount of waste polymer produced during reformulation and packaging due to spills, drum residues and cleaning is expected to be less than approximately 3% of the import volume. A further 5% of the notified polymer is expected to remain as residues in consumer packaging and is expected to be disposed of to domestic landfill. It is assumed that the remaining proportion of the notified polymer will be released to sewer throughout Australia after end-use as a result of the washing of skin and hair.

The notified polymer is expected to be hydrolytically stable within the environmental pH range, as supported by the submitted hydrolysis test, and to not be readily biodegradable. Due to its high molecular weight and hence inability to cross biological membranes, the notified polymer is not expected to bioaccumulate.

The notified polymer is moderately soluble in water, but due to its anionic nature, is likely to be immobilised

via adsorption onto soil particles and sediments in landfill and sewage treatment plants, eventually degrading through biotic and abiotic processes to form various oxides of carbon as well as water.

Under a worst case scenario with 100% release to the aquatic environment, and no removal within STPs, the Predicted Environmental Concentration has been calculated as follows:

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	6,000	kg/year
Proportion expected to be released to sewer	100.000%	
Annual quantity of chemical released to sewer	6,000.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	16.44	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.88	µg/L
PEC - Ocean:	0.39	µg/L

The Risk Quotient (Q) has been derived by dividing the PEC by the PNEC:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	3.88	8.6	0.452
Q - Ocean:	0.39	8.6	0.045

As the Q value is below 1 for both river and ocean, it can be concluded that the risk to the aquatic environment from the proposed use pattern and maximum import volume is considered to be acceptable.

Extrapolating from the above calculations, and using the same assumptions and scenario, the maximum import volume limit that maintains a Q value ≤ 1 is shown in the following table:

<i>Secondary Notification Limit Volume</i>	<i>Limit(Max)</i>	<i>Limit(Practical)</i>
Q - River:	13,285 kg/y	13,250 kg/y
Q - Ocean:	132,849 kg/y	132,750 kg/y

This, however, overlooks the fact that only approximately 25% of effluent is released to freshwater in Australia and assuming an even usage, the volume limit is closer to 50 t/y.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1300 kg/m³). Using these assumptions, irrigation with a concentration of 3.884 µg/L may potentially result in a soil concentration of approximately 2.988×10^{-2} mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.494×10^{-1} mg/kg and 2.988×10^{-1} mg/kg, respectively.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

Based on the reported use pattern, the notified polymer is not considered 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 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.
 - the introduction volume of the notified polymer exceeds 50 tonnes.
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component in personal care products, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 6 tonnes, 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 chemical 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 a product containing 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.