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

FULL PUBLIC REPORT

Polymer in Aculyn 28

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**Director
Chemicals Notification and Assessment**

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION.....	5
5. PROCESS AND RELEASE INFORMATION.....	5
5.1. Operation Description.....	5
6. EXPOSURE INFORMATION	6
6.1. Summary of Environmental Exposure.....	6
Fate.....	6
6.2. Summary of Occupational Exposure	6
6.3. Summary of Public Exposure	6
7. PHYSICAL AND CHEMICAL PROPERTIES.....	6
8. HUMAN HEALTH IMPLICATIONS.....	7
8.1. Toxicology	7
8.2. Human Health Hazard Assessment.....	7
9. ENVIRONMENTAL HAZARDS.....	7
9.1. Ecotoxicology	7
9.2. Environmental Hazard Assessment	7
10. RISK ASSESSMENT.....	8
10.1. Environment	8
10.2. Occupational health and safety	8
10.3. Public health	8
11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS	8
11.1. Environmental risk assessment	8
11.2. Human health risk assessment	9
11.2.1. Occupational health and safety.....	9
11.2.2. Public health.....	9
12. MATERIAL SAFETY DATA SHEET	9
12.1. Material Safety Data Sheet	9
13. RECOMMENDATIONS.....	9
13.1. Secondary notification	10
14. BIBLIOGRAPHY	10

FULL PUBLIC REPORT**Polymer in Aculyn 28****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Rohm & Haas Australia Pty Ltd (ABN 29 004 513 188)

4th Floor

969 Burke Road

Camberwell VIC 3124

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 and Structural Formulae, Molecular Weight, Charge density, Polymer Constituents, Residual monomers and Impurities, Reactive functional groups and Manufacture/Import Volume.

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 28

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Molecular Weight Requirements	Yes
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

The notified polymer will be imported in 205 L plastic drums as a component of polymer dispersion, Aculyn 28, at a concentration of <30% w/w. The polymer dispersion transported by road to the notifier's warehouse prior to distribution by road to cosmetic formulators, where it will be incorporated in cosmetic products for consumer use. The formulated cosmetic products will be packed in a variety of glass and plastic bottles and jars ranging from 50 to 500 mL size containers. It will be distributed by road to retail outlets and hair salon outlets. The notified polymer will be present in the cosmetic products at a concentration of 0.2 to 0.5%.

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>	3-10	3-10	3-10	3-10	3-10

USE

The notified polymer is used as a thickener in cosmetic products including hair gels, shampoos, creams and lotions.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported into Australia as a component of polymer dispersion in water containing <30% notified polymer. During warehousing and shipping, workers will handle the polymer dispersion in their original packaging in sealed plastic drums.

The polymer dispersion will be distributed to cosmetic formulators for reformulation into cosmetic products. During reformulation, the polymer dispersion will be gravity fed or pumped from the plastic drums into a stainless mixing vessel of 500 to 2000 L capacity. Alternatively, the polymer dispersion will be weighed and the requisite amount is manually poured into the stainless mixing vessel. Mixing is achieved by slow mechanical stirring. Other ingredients will also be added and the resulting mixture is tested for quality control. Laboratory technicians will wear impervious gloves, laboratory coats and safety glasses.

Once the laboratory technician approves the specifications of the product quality, the cosmetic product is pumped from the mixing vessel to a holding tank prior to packaging in 50 to 500 mL size containers. Filling and packaging operation are automated and enclosed, and involves automated filling, capping and labelling. The cosmetic products will contain 0.2 to 0.5% notified polymer.

During reformulation, workers who come into contact with the polymer dispersion and cosmetic products containing it will wear safety glasses, impervious gloves, coveralls (or similar apparel) and safety boots. The mixing vessels and the filling machines are fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source.

The cosmetic product will be sold to retail outlets for consumer use and will also be available to hair salons. Hairdressers, beauticians and similar workers will apply the cosmetic products to hair and skin of clients. The type of personal protective equipment used by these workers varies. However, in most cases the product will be applied by hand, therefore, workers are expected to wear impervious gloves.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

During the formulation of cosmetic preparations the estimated annual losses of notified polymer are:

Spills	less than 1%	<100 kg
Equipment cleaning	less than 2%	<200 kg
<u>Import container residuals</u>	<u>less than 1%</u>	<u><100 kg</u>
Total Annual Loss due to formulation		<400 kg

The majority of the notified polymer will be incorporated into the cosmetic preparations and will be released to the environment during personal washing. Approximately 1% of the end product will remain in the empty end-use container, this equates to less than 100 kg of notified polymer annually.

Fate

Any spilt and clean-up material will go to landfill. The empty import drums, including any residual polymer, will either go to drum reconditioners or landfill. The equipment cleaning effluent, containing any notified polymer, will go to on site treatment plants where the effluent will be treated with flocculants with the resultant solids (containing the majority of the notified polymer present in the washing effluent) going to landfill and the effluent being released to sewer.

During personal washing, the cosmetic preparation will be washed down the drain thus releasing the majority (up to 95%) of the imported notified polymer to sewer. The end-use container, containing any residual material will be disposed into general waste, which will go to landfill.

In landfill or in the sewer, the notified polymer will adsorb to the soil, suspended particles, or sediment due to its anionic nature. Despite the presence of theoretically hydrolysable groups, the polymer is not expected to hydrolyse over the environmental pH range of 4-9, but, over time, the polymer will degrade via biotic and abiotic processes to water and oxides of carbon.

6.2. Summary of Occupational Exposure

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, beauticians and similar workers. Exposure to the notified polymer will be predominantly dermal. However, the low concentration of the notified polymer and the use of gloves when applying the cosmetic product would ensure low occupational exposure.

Transport, storage and retail workers will handle sealed containers or retail packaging and are unlikely to be exposed to the notified polymer except when packaging is damaged or accidentally breached.

6.3. Summary of Public Exposure

Cosmetic products containing the notified polymer are for sale to the general public. Public exposure will result through use of the cosmetic products containing a maximum of 0.5% notified polymer. Consumer will apply the product on the hair or body twice daily. The maximum quantity of the product used per application is 12 grams (0.06 grams notified polymer/application or 0.12 grams notified polymer/day). Public exposure will be low, based on the above estimated exposure.

7. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties described below are for the polymer dispersion in water, unless otherwise stated.

Appearance at 20°C and 101.3 kPa

Melting Point

Density

Water Solubility

White opaque flowing dispersion in water

>100°C

1010 kg/m³, 1050 kg/m³ (polymer)

Insoluble in water at pH 2-3, while at pH 6-8 the polymer is soluble in water.

Dissociation Constant	The polymer is anionic. It is unlikely to undergo further dissociation in the environmental pH range 6-9. The polymer will form neutral carboxylic acid groups at low pHs (4-5).
Reactivity	The notified polymer is expected to be stable under normal conditions of use.
Degradation Products	None known

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral LD50 >5000 mg/kg bw	low toxicity	no	no
Rat, acute dermal LD50 >5000 mg/kg bw	low toxicity	no	no
Rabbit, skin irritation	slightly irritating	no	yes
Rabbit, eye irritation	slightly irritating	no	yes

Very slight to well defined erythema and very slight oedema were observed in the skin irritation study. However, erythema was no longer evident by day 7 observation period and oedema was resolved by 48 hours. Transient conjunctival effects were observed in the eye irritation study. All eyes returned to normal by 48 hours.

Overall, the observed effects were indicative of low hazard.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The limited studies provided support this conclusion.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

Generally this type of polyanionic polymer will not be toxic to fish and daphnids with $LC_{50} > 100$ mg/L. However, there may be indirect toxicity to algae due to the chelation by the polymer of growth nutrients required by the algae. The degree of toxicity appears to be related to the distance between acid groups. The most toxic form is when there is one carbon separating the acid groups, 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. The notified polymer does contain a significant proportion of acid groups separated by 1 carbon, thus potential algae toxicity may exist. (Boethling and Nabholz, 1997).

9.2. Environmental Hazard Assessment

Since no ecotoxicological data was provided, a quantitative assessment using the Boethling and Nabholz reference (fish and daphnid $LC_{50} > 100$ mg/L and geometric mean algae $EC_{50} = 8.6$ mg/L) and a safety factor of 1000 was conducted. The resultant PNEC (LC_{50} of most sensitive species/safety factor) was 8.6 µg/L.

Due to the high molecular weight and chemical nature of the notified polymer, it is not likely to bioaccumulate.

10. RISK ASSESSMENT

10.1. Environment

Based on the import of <10000 kg per annum of the notified polymer, and assuming the majority (95%) of this is eventually released to sewer and not removed during sewage treatment processes, the following Predicted Environmental Concentration (PEC) can be estimated

Amount of notified polymer entering sewer annually	<9500 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365

$$\begin{aligned}\text{PEC}_{\text{sewer}} &= \frac{9\,500\,000\,000 \text{ mg}}{20\,000\,000 \times 200 \times 365 \text{ L}} \\ &= 0.0065 \text{ mg/L} \\ &= 6.5 \text{ }\mu\text{g/L}\end{aligned}$$

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 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.

Using the above PNEC estimation and the calculated PEC, a risk quotient ($\text{RQ} = \text{PEC}/\text{PNEC}$) can be estimated, $\text{RQ} = 6.5/8.6 = 0.76$. With quotient (RQ) less than 1 and based on the proposed use pattern of the notified polymer, the amount being imported and the nationwide use of the products and subsequent diffuse release, it is not expected to pose an unacceptable risk to aquatic life. The above RQ is based on conservative assumptions of volume introduced and toxicity, and on undiluted total release to inland waters. It is likely that a significant amount would be removed from the water column through adsorption to sludge and sediments, thus reducing RQ.

10.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

10.3. Public health

Members of the public will make dermal contact with the cosmetic products containing the notified polymer.

During use, 12 grams of the product is expected to be applied twice daily by dermal route. Assuming 20% of the product (containing 0.5% notified polymer) is absorbed by the skin, the consumer would be exposed to 0.024 g/day notified polymer, which is equivalent to a systemic exposure of 0.4 mg/kg bw for a 60 kg female, which is much lower compared with the acute dermal LD50 in rats (>5000 mg/kg bw), and would provide an adequate margin of safety.

Based on the expected low toxicological hazard, low exposure during use, and the low concentration of the notified polymer in cosmetic products, exposure to public health is considered low.

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 Low Concern to public health when used as a component of cosmetic products.

12. MATERIAL SAFETY DATA SHEET

12.1. 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

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Exhaust ventilation during cosmetic product manufacture and filling operations
 - Enclosed and automated mixing and filling operations
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid spills and splashes during manual transfer of the polymer into the mixing vessel and during cleaning operations.
- Employers should implement the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Overalls (or similar protective apparel)
 - Safety glasses
 - Safety footwear
 - Impervious gloves

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 formulator to minimise environmental exposure during formulation of the notified polymer:
 - Use only in bunded areas with only process drains within the work area.

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

- Spills or release of the notified polymer should be handled by containment and adsorbed with inert material.

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.
 - the import quantities increase to >10 tonnes/annum, at which level the potential aquatic risk presented by the notified polymer will need to be reassessed.

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.

14. BIBLIOGRAPHY

Boethling and Nabholz (1997). Environmental Assessment of Polymers under the US Toxic Substances Control Act, in Hamilton JD and Sutcliffe R (eds): Ecological Assessment of Polymers. ITP, USA.