

File No PLC/440

14 May 2004

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

**FULL PUBLIC REPORT**

**Disodium PEG-12 dimethicone sulfosuccinate**

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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24 June 2004

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**Director  
Chemicals Notification and Assessment**

**FULL PUBLIC REPORT****Disodium PEG-12 dimethicone sulfosuccinate****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Alberto Culver (Australia) Pty Ltd (ABN 54 000 180 146)  
14 Loyalty Road  
North Rocks NSW 2151;

Capitol Ingredients Australia Pty Ltd (ABN 30 055 147 567)  
Suite 6  
10 Gladstone Road  
Castle Hill NSW 2154; and

Unilever Australia Limited (ABN 66 004 050 828)  
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;  
CAS Number;  
Molecular and Structural Formulae;  
Molecular Weight; and  
Polymer Constituents

## 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)

Commercial Evaluation Permit No 386 issued on 1 June 1999

## NOTIFICATION IN OTHER COUNTRIES

None

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

Mackanate DC30 / Mackanate DC50

### 3. COMPOSITION

PLC CRITERIA JUSTIFICATION		
Functional Group	Category	Equivalent Weight (FGEW)
Carboxylate	Low Concern	400

<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 not be manufactured in Australia. It will be imported as a polymer concentrate in water and will be sold to formulators for the manufacture of foaming and hair care products. Alternatively, the notified polymer will be imported as a component of ready to use foaming and hair care products. Depending on the type of end use, the notified polymer will be present at <1% in the finished products.

#### 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>	1.5	1.5	1.5	1.5	1.5

#### USE

The notified polymer will be used as a component of cosmetic foaming cleansers, shampoos and other mild foaming products.

### 5. PROCESS AND RELEASE INFORMATION

#### 5.1. Operation Description

The notified polymer will be imported in Australia as a premix concentrate in water. The concentrate containing 30% or 50% notified polymer would be transported by road in 204 kg drums. It will be sold and distributed to formulators, who subsequently will incorporate the polymer concentrate into foaming and hair care products.

During formulation, the notified polymer is manually weighed and dispensed into plastic beakers where the required volume is transferred into a mixing vessel. Mixing operations are described to be enclosed and automated. Prior to packaging, sampling and quality testing of the formulated product is carried out in the laboratory. The formulated products will then be transferred by pump into a storage tank connected to a multiple head filler machine and automatically poured into 150 to 200 mL screw cap or push on caps plastic bottles. The finished products will contain <1% notified polymer.

The bottled products will be packed in cardboard cartons and will be distributed by road to retail outlets for consumer use.

Alternatively, the notified polymer will be imported as a component of ready to use foaming and hair care products, for distribution to retail outlets for consumer use. Retail workers will handle the finished products in their retail packaging.

## 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%	<15 kg
Equipment cleaning	3% max	45 kg
<u>Import container residuals</u>	<u>less than 1%</u>	<u>&lt;15 kg</u>
Total Annual Loss		<75 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 use product will remain in the empty end-use container, this equates to less than 15 kg of notified polymer annually.

#### Fate

Any spilt material, clean-up material and container linings with any residual material will be sent to landfill. The equipment cleaning effluent, containing any notified polymer, will go to on-site holding/treatment tanks and will then be released to sewer. The end-use container, containing any residual material, will be disposed of into general waste, which will go to landfill. Due to its water solubility the notified polymer may leach from landfill but this will be at very low concentrations and in a diffuse manner.

Approximately 94% of the notified polymer will enter the sewer due to personal washing. In sewer, the polymer is likely to remain in the water column due to its high water solubility. However, it is a surfactant and may partition to the sediment and become adsorbed due to its negative charge.

While the polymer contains a hydrolysable functionality this is unlikely to occur under ambient conditions in the environmental pH range of 4-9. The notified polymer is not likely to be readily biodegradable but will slowly degrade over time by abiotic and biotic processes to water, silica and oxides of carbon and sulphur.

### 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.

During transport and storage, warehouse workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Similarly, retail workers will handle the products in their retail packaging, therefore exposure is not expected unless the packaging are punctured or damaged.

### 6.3. Summary of Public Exposure

The products containing the notified polymer 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. However, exposure will be low because the notified polymer is present at low concentrations.

## 7. PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Appearance at 20°C and 101.3 kPa</b>	White to pale yellow clear liquid
<b>Boiling Temperature</b>	100°C (water)
<b>Density</b>	1100 kg/m <sup>3</sup> (30% polymer concentrate); 1150 kg/m <sup>3</sup> (50% polymer concentrate)
<b>Water Solubility</b>	The polymer is >50% water soluble as it is imported

	as a 50% solution. Clearly the normally insoluble silicone portion is outweighed by the large polar functionality.
<b>Dissociation Constant</b>	The polymer contains a strong acid group that will remain dissociated in the environmental pH range 4-9, while the less acidic group will form the neutral free acid at low pH (4-5).
<b>Reactivity</b>	The notified polymer is expected to be stable under normal conditions of use. However, the polymer should be kept away from strong oxidising agents and open flames.
<b>Degradation Products</b>	None known

## 8. HUMAN HEALTH IMPLICATIONS

### 8.1. Toxicology

The following toxicological study reports 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
Rabbit, skin irritation (50% notified polymer)	slightly irritating	no	yes
Rabbit, eye irritation (50% notified polymer)	slightly irritating	no	yes
Guinea pig, skin sensitisation (30% notified polymer)– similar to adjuvant test	limited evidence of sensitisation.	no	yes

There are three eye irritation and two skin irritation studies submitted, all of which were conducted on 50% polymer concentrate in water. All studies reveal transient corneal opacity, erythema and/or oedema.

During the skin sensitisation study, slight skin reaction was observed in three male animals on the 9<sup>th</sup> day of dosing using 30% notified polymer. Also, one female animal died after the 5<sup>th</sup> day of dosing. Necropsy suggests that the death was not dose related, rather due to intestinal disorder.

Overall, the observed effects from the above studies 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 submitted toxicity data support the conclusion of low hazard.

## 9. ENVIRONMENTAL HAZARDS

### 9.1. Ecotoxicology

No ecotoxicological data were submitted for the notified polymer. However, data for a surrogate group of low molecular weight sulfosuccinates were submitted. The surrogate data are not ideal for the notified polymer, in that the chemicals are not closely similar structurally and are relatively insoluble dialkyl ester sulfosuccinates, as opposed to the mono polyoxyethylene silicone ester functional group in the notified polymer. The data will be used in this assessment but it needs to be acknowledged that it will only provide some general indication of the toxicity of the notified polymer.

The surrogate group consisted of three low molecular weight sulfosuccinates:

- Succinic acid, sulfo-, 1,4-bis(2-ethylhexyl) ester, sodium salt Designated as "Ethylhexyl ester." CAS No. 577-1 1-7
- Succinic acid, sulfo-, 1,4-bis( 1,3-dimethylbutyl)ester, sodium salt Designated as "Dimethylbutyl ester." CAS No. 2373-38-8
- Succinic acid, sulfo-, 1,4-bis(dicyclohexyl)ester, sodium salt Designated as "Cyclohexyl ester." CAS No. 23386-52-9

The surrogate acute toxicity data taken from the High Production Volume (HPV) Chemicals Test Plan for Sulfosuccinates Category (<http://www.epa.gov/chemrtk/cyclodim/c13133.pdf>) are:

	Ethylhexyl ester	Dimethylbutyl ester	Cyclohexyl ester
Water solubility at 25°C	15 g/L	300-320 g/L	120 g/L
Fish toxicity 96 h LC <sub>50</sub> mg/L	bluegill 37 trout 28	bluegill >1000 trout 1200	bluegill 470
Daphnia toxicity 48 h EC <sub>50</sub> mg/L	36.2	Not determined	457
Algae toxicity determined,	Not determined	Not determined	No EC

growth stimulated

As can be seen toxicity seems to be closely related to solubility, with the least soluble surrogate being slightly toxic to fish and daphnia compared to the others, which are practically non-toxic to these organisms. Since the notified polymer is >50% water soluble this suggests that toxicity to fish and daphnia should be low if toxicity is through baseline narcosis rather than any special mechanism.

## 9.2. Environmental Hazard Assessment

A true PNEC cannot be determined since ecotoxicity data for the notified polymer were not submitted. However, using the surrogate data a rough indication may be obtained. A safety factor of 1000 is used, since there is no data for three trophic levels, and the most sensitive species is trout with EC<sub>50</sub> of 28 mg/L. The PNEC (EC<sub>50</sub>/safety factor) is 28 µg/L.

Due to the molecular weight and nature of the polymer it is not expected to bioaccumulate.

## 10. RISK ASSESSMENT

### 10.1. Environment

Based on the import of 1500 kg per annum of the notified polymer, and assuming the majority (94%) 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	1410 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365

$$\begin{aligned} \text{PEC}_{\text{sewer}} &= \frac{1\,410\,000\,000 \text{ mg}}{20\,000\,000 \times 200 \times 365 \text{ L}} \\ &= 0.00097 \text{ mg/L} \\ &= 0.97 \text{ µg/L} \end{aligned}$$

When released to receiving waters (ocean) the concentration is generally assumed 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 released to receiving waters will be assumed as a worst-case estimate.

The estimated risk quotient (RQ = PEC/PNEC) is  $0.97/28 = 0.035$ . As RQ is much less than 1, and assuming that the notified polymer is less toxic than the surrogate used for the PNEC estimate, and based on the proposed use pattern, 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.

## 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 and possibly accidental ocular contact with the foaming and hair care products containing the notified polymer. Although the notified polymer may be slight eye and skin irritant, it is present at very low concentrations in the foaming and hair care products. It is also a normal practice to minimise eye contact with the products.

Since the polymer content in the finished product is low (<1%) and the non-hazardous nature of the polymer, the risk to public health is 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 foaming and hair care 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

- 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 formulator to minimise environmental exposure during formulation of the notified polymer:
  - All process areas should be bunded with only process drains within the area.

## Disposal

- The notified polymer should be disposed of to landfill.

## Emergency procedures

- Spills/release of the notified polymer should be handled by containment and use of inert absorbent. The absorbent should then be placed in a sealable and labelled container and disposed of to landfill.

**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.