

File No PLC/567

August 2005

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

**FULL PUBLIC REPORT**

**Siloxanes and Silicones, di-Me, 3- hydroxypropyl Me, ethers with polyethylene glycol  
monoeicosanoate**

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**

**NICNAS**

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**FULL PUBLIC REPORT****Siloxanes and Silicones, di-Me, 3- hydroxypropyl Me, ethers with polyethylene glycol monoecosanoate****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

Capitol Ingredients Australia Pty Ltd (ABN 30 055 147 567) of Unit 9, 7 Meridian Place, Norwest Business Park BellaVista NSW 2153; and

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

## NOTIFICATION CATEGORY

Polymer of Low Concern.

## EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

## 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)

No

## NOTIFICATION IN OTHER COUNTRIES

No

**2. IDENTITY OF CHEMICAL**

## CHEMICAL NAME

Siloxanes and Silicones, di-Me, 3- hydroxypropyl Me, ethers with polyethylene glycol monoecosanoate

## OTHER NAME(S)

Dimethicone PEG-8 Meadowfoamate

## MARKETING NAME(S)

Fancorsil LIM-1

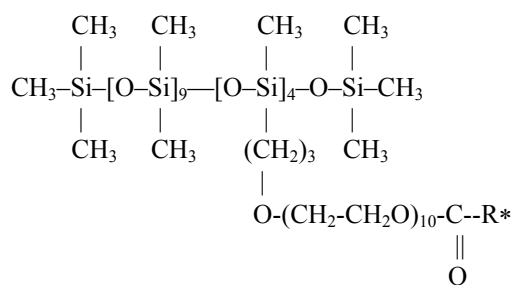
## CAS NUMBER

157479-51-1

## MOLECULAR FORMULA

Unspecified

## STRUCTURAL FORMULA



R\* refers to the fatty acids derived from meadowfoam seed oil.

MOLECULAR WEIGHT (MW)	
Number Average Molecular Weight (NAMW)	2788
Weight Average Molecular Weight (WAMW)	4426
Polydispersity Index (WAMW/NAMW)	1.59
% of Low MW Species < 1000	5.26
% of Low MW Species < 500	0.68

### 3. COMPOSITION

#### POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Siloxanes and silicones, dimethyl, 3-hydroxypropyl methyl, ethoxylated	68937-54-2	83.0	< 1
Poly(oxy-1,2-ethanediyl), alpha-2-propenyl-omega-hydroxy-Glycerides, <i>Limnanthes alba</i>	27274-31-3 153065-40-8	11.0 6.0	< 1 < 1

#### PLC CRITERIA JUSTIFICATION

The notified polymer contains no medium or high concern functional groups.

<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
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. INTRODUCTION AND USE INFORMATION

#### MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Tresemme Smoothing Serum containing the notified polymer at 2% will be imported in 200 mL plastic bottles suitable for retail sale. The 100% pure notified polymer will be imported in 200 L steel drums or 15 L pails. These drums or pails will be transported by road from the wharf to the notifier's site.

#### 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>

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<i>Tonnes</i>	1	1	1	1	1
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## USE

Conditioning and moisturising agent in cosmetics (lipsticks, shampoos, conditioners, creams and lotions, hair products) .

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Operation Description

The notified chemical will initially be imported as an ingredient of the lotion Tresemme Smoothing Serum at a concentration of 2%, for retail sale. Initially, there will be no reformulation or repackaging in Australia. But at a later stage, the notified polymer will be imported in pure form (100%) and Tresemme Smoothing Serum and other cosmetic products will be produced and packaged in Australia.

#### Formulation of Tresemme Smoothing Serum

Tresemme Smoothing Serum will be formulated at the North Rocks site of Alberto Culver. Formulation will occur once per month using a batch process. Approximately 20 kg of the notified polymer will be used to formulate each batch of Tresemme Smoothing Serum.

During formulation, the drums or pails containing notified polymer will be transferred on a pallet by forklift from the warehouse area to the mixing area. The drum or pails will be placed on scales and a dip tube used to transfer the required amount of notified polymer from the drum or pail to a closed blending vessel. Inside the blending vessel, the notified polymer will be mixed with water and other ingredients such as stabilisers, colour and fragrance to form Tresemme Smoothing Serum. Blending will take approximately two hours.

At the end of the blending process, a sample of Tresemme Smoothing Serum will be manually taken for quality control.

Once formulated, Tresemme Smoothing Serum will be transferred from the blending vessel to 200 mL plastic bottles using an automated filling line, which places and seals caps on the bottles automatically. Packaging workers will place these bottles manually into cardboard cartons, each carton holding 12 bottles. Cartons will be loaded onto a pallet, and transferred back to the general warehouse area for storage until they are transported to the retailer's warehouse.

The blending vessel and filling lines will be cleaned after the formulation of each batch by flushing the system with water. Cleaning residues will be sent to the waste water pit on the North Rocks site. After emptying, the drums containing the notified polymer will be sent to a drum recycler, and the pail sent back to the manufacturer of the notified chemical.

During end-use by the public, users of Tresemme Smoothing Serum are instructed to rub one or two walnut size amounts onto wet hair. The consumer would then, at a later time, wash hair with shampoo and the diluted conditioner would be disposed down the drain.

The imported polymer will also be used in lipsticks, creams and lotions that will be used by the public.

## 6. EXPOSURE INFORMATION

### 6.1. Summary of Occupational Exposure

Transport and warehouse workers for both ready to use imported product (containing 2% notified polymer) and imported 100% notified polymer, will not be exposed to the notified polymer unless the packaging is accidentally breached.

The notifier provided information of the formulation of Tresemme Smoothing Serum. During the formulation process, the occupational exposures will be as follows:

- Compounders could be exposed to the notified polymer while opening and closing drums,

weighing of the notified polymer, transferring the notified polymer into the mixing vessel, and cleaning the vessels after use. The possible routes of exposure are via dermal, inhalation and accidental eye contact.

- The Chemist who would sample and test the ingredient for QA purposes could be exposed to the notified polymer. The possible routes of exposure are dermal, inhalation and accidental eye contact.
- The packers who would monitor the line filler and the capper could be exposed to the notified polymer at 2% in the finished product. The possible routes of exposure are dermal, inhalation and accidental eye contact.

However, exposure to the notified polymer is limited because of the engineering controls, isolation process and the personal protective equipment worn by workers.

While end-use of the notified polymer is expected to be primarily in consumer products, some occupational exposure could occur to hairdressers or beauticians if products were formulated for salon use. Repeated dermal exposure could occur during application of the product to clients, and such exposure would be greatly reduced by use of gloves.

Retail workers will handle the products in their retail packaging, therefore exposure is not expected unless the packaging are punctured or damaged.

At this stage the notifier could not provide details on other uses. However, The notifier states that the maximum concentration of the notified polymer in the final products will not exceed 5%.

## **6.2. Summary of Public Exposure**

The products containing the notified polymer are for sale to the general public. Members of the public will have dermal exposure and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be reduced because the notified polymer is present at 5% or less.

## **6.3. Summary of Environmental Exposure**

### **6.3.1. Environmental Release**

There may be release of the polymer when formulated from Fancorsil Lim-1 into Tresemme Smoothing Serum . The process described above is a simple blending process conducted within a closed system. Consequently, release to the atmosphere is expected to be negligible.

Release to water will occur during cleaning operations where flushings are sent to the on site waste water pit. It is expected any significant spillage will also be flushed on to onsite waste water pit where the water will be treated prior to disposal to sewer.

It is difficult to predict actual release figures during these operations. However, the European Commission Technical Guidance Document (EC, 1996) estimates for a chemical with this high level of solubility, a release fraction of 0.003 to water may be applied. Assuming the entire maximum import volume of 1 tonne is used in the formulation process and formulation occurs for 300 days of the year, the release to water per day of operation is 10 g.

Direct release to soil is expected to be negligible. Some of the notified polymer may be associated with sludge from the on site waste water pit, but this is likely to be incinerated which would destroy the notified polymer.

Given the use pattern of the notified polymer, initial release is entirely expected to occur to the aquatic compartment. Assuming the maximum importation volume per year of 1000kg and all cleaning operations using the notified polymer occur all year, the average daily release is expected to be very low. This release is expected to be relatively diffuse.

While direct release is likely to be the aquatic compartment. It is difficult to consider which environmental medium the polymer will finally reside in without considering the fate of the substance. The nature of surfactants indicates they could associate with sludge due to hydrophobic moieties or remain in solution due to hydrophilic moieties. Consequently, once in the sewerage treatment plant, the chemical may end up in receiving waters or most will associate with sludge where it could be

incinerated, or in some cases, applied to agricultural land.

### 6.3.2. Environmental Fate

During formulation, empty drums are sent to a drum recycler, while empty pails are returned to the manufacturer of the notified polymer.

End use of the chemical remains primarily in the public domain with the products containing the notified polymer being sold in relatively small containers (200mL). There is unlikely to be much residual product in containers as they will probably be flushed with water prior to disposing of the container. Therefore, no disposal recommendations are made with respect to end use.

Residual polymer disposed of to landfill in empty containers is expected to be absorbed to soil particles and will eventually be degraded through biological and abiotic processes. When released into the sewer, the polymer should absorb onto sediments/sludge due to its low water solubility. Although not readily biodegradable, the notified polymer absorbed onto sewerage sludge is likely to be gradually degraded to natural components.

The low water solubility of the notified polymer may indicate a potential for bioaccumulation. However, the high molecular weight will limit bioaccumulation.

## 7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Clear to off-white to yellow liquid
Melting Point/Glass Transition Temp	Not available
Density	1.05 -1.1 kg/m <sup>3</sup> at 20°C
Water Solubility	Gives a clear solution at 20°C, but likely to be water dispersible rather than truly soluble as the hydrophobic constituents outweigh the hydrophilic constituents.
Dissociation Constant	Not expected to dissociate.
Reactivity	Low

## 8. HUMAN HEALTH IMPLICATIONS

### 8.1. Toxicology

The following toxicological end-points were submitted:

- |   |  |
|---|--|
| • Acute oral toxicity (rat)                                 | LD <sub>50</sub> >5000 mg/kg   |
| • Acute skin irritation (rabbit)                            | not irritant   |
| • Acute eye irritation (rabbit)                             | not irritant   |
| • Skin sensitization (patch test)                           | non sensitising  |
| • Ames (Salmonella/Escherichia) test and Mutagenicity test: | No detectable genotoxic activity, in the presence or absence of enzyme activation. |

All results 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.

## 9. ENVIRONMENTAL HAZARDS

### 9.1. Ecotoxicology

No toxicological data were submitted.

### 9.2. Environmental Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is confirmed by studies on the effect of polydimethylsiloxanes on organisms in the environment which demonstrate they have no adverse effects or only very limited toxic effects.

## 10. RISK ASSESSMENT

### 10.1. Environment

Transport of the Notified Polymer Prior to Formulation. This is not likely to constitute a major hazard, the material is likely to be containerised, or in packaging designed to withstand impact. Accidental spills during transportation should be relatively easily recovered and disposed of, as described under Environmental Emergency Procedures.

Storage & Product Formulation. With the relatively low use level proposed for this product, and its formulation and dispensing in closed systems, it is unlikely that there will be any significant release to the environment. Accidental releases during product formulation are unlikely to present a major hazard and should be dealt with as described under Occupational Emergency Procedures.

In a formulated product, the process is a batch process with a batch typically 1 tonne with each batch containing 20kg of the notified chemical being produced in 4 hours, 12 batches per year. Emissions to waste water are possible while cleaning the equipment. It is estimated that 2-3% final product are rinsed into the waste water which then goes to a biological plant.

This release is expected to be relatively diffuse and some further calculations are shown below.

While direct release is likely to be to the aquatic compartment, it is difficult to consider which environmental medium the chemical will finally reside in without considering the fate of the substance. The nature of creams and lotions indicates they could associate with sludge due to hydrophobic moieties or remain in solution due to hydrophobic moieties.

Consequently, once in the sewerage treatment plant, the notified polymer may end up in receiving waters or most will associate with sludge where it could be incinerated, or in some cases, applied to agricultural land.

A small amount of the notified polymer (<1.0%) will remain in containers and will be disposed of to land-fill via normal household rubbish collection. This would result in approximately 10kg of the notified polymer released in the environment through disposal in landfill.

Risk Assessment. Since most of the notified polymer will enter the sewer, under a worst-case scenario with no removal of the notified polymer, in the sewerage treatment plant, the resultant predicted environmental concentration (PEC) in sewerage effluent on a nationwide basis is estimated to be 0.68 µg/L.

Amount entering sewer annually	1000 kg
Population of Australia	20.1 Million
Amount of water used per person per day	200 L
Number of days in a year	365
Concentration in sewer effluent	0.68 µg/L.

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PEC of the notified chemical in freshwater and marine water may approximate 0.68 or 0.07 µg/L. respectively.

A predicted no effect concentration (PNEC) could not be calculated as no ecotoxicity data are available. However, based on type and structure of the notified polymer, it is not expected to be toxic to aquatic organisms and there should be a wide safety margin. Bioaccumulation is not expected from the diffuse use pattern and low import volume.



Therefore, based on the proposed use pattern, the notified polymer is not expected to pose an unacceptable risk to the health of aquatic life.

The treatment plant of the formulation site will be managed according to the requirements of Sydney Water or their equivalent. Given the use pattern of the notified chemical, initial release is entirely expected to occur to the aquatic compartment. Assuming the maximum importation volume of 1000kg of notified chemical and use of the notified chemical occurring all year, the average daily release is expected to be 0.08 kg. The content of emitted (E) is  $1000 \text{ kg} \times 3\%/365 = 0.08 \text{ kg}$  per day over a period of 1 year.

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

## **10.2. Occupational Health and Safety**

Worker exposure at the formulation plant to the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers. The notified polymer is present in the product at a relatively low concentration, reducing potential exposure to salon workers. It is of high molecular weight (NAMW approximately 2788) and low vapour pressure. Toxicological information provided by the notifier indicates that the notified polymer is non-hazardous. The notifier also states that no clinical symptoms of exposure to the polymer have been reported overseas. Therefore, based on the expected low toxicity and the use of PPE, occupational risk from the use of the notified polymer is considered to be low.

## **10.3. Public Health**

As the notified polymer will be used in hair and skin care products which are available throughout Australia in small containers, public exposure is expected to be widespread. Dermal and inhalation contact is expected to be likely the main route of exposure. However, given the small amounts used per application, the expected low toxicity and the low concentration of the polymer in the product, the public risk is expected to be 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 in the proposed manner.

## **12. MATERIAL SAFETY DATA SHEET**

### **12.1. Material Safety Data Sheet**

The notifier has provided MSDS for the notified chemical and a product containing it 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 or work practices 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.
- Employers should ensure that the following personal protective equipment is used by plant operators and quality assurance staff to minimise occupational exposure to the polymer:
  - Coveralls/laboratory coats;
  - Protective gloves;
  - Safety goggles/glasses; and
  - Safety boots.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS will be 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 measure should be implemented by the notifier to minimise environmental exposure during formulation of the notified polymer:
  - Bunding

##### Disposal

- The notified polymer should be disposed of to landfill or incinerated.
- Empty containers should be sent to local recycling or waste disposal facilities.

##### Storage

- The notified chemical should be stored in sealed containers under normal cool, dry warehouse conditions.
- The product should be in cool dry storage, protected from freezing and kept out of the reach of children.

##### Emergency procedures

- Spills/release of the notified polymer should be handled by absorbing with sand and put into suitable containers for disposal. Contaminated containers can be re-used after cleaning.

#### 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.
  - concentration of the notified polymer in personal care products exceeds 5%.

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.