

File No SAPLC/67

30 July 2007

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

FULL PUBLIC REPORT

Polymer in Arlypon TT

This Self Assessment has been compiled by the applicant and adopted by NICNAS 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), administered by the Department of Health and Ageing and the Department of the Environment and Water Resources has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	3
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	4
6.1. Exposure Assessment	4
6.2. Toxicological Hazard Characterisation	5
7. ENVIRONMENTAL IMPLICATIONS	5
7.1. Exposure Assessment	5
7.2. Environmental Hazard Characterisation	6
7.3. Environmental Risk Assessment	6
8. CONCLUSIONS	6
8.1. Level of Concern for Occupational Health and Safety	6
8.2. Level of Concern for Public Health	6
8.3. Level of Concern for the Environment	6
9. MATERIAL SAFETY DATA SHEET	6
9.1. Material Safety Data Sheet	6
10. RECOMMENDATIONS	7
11. REGULATORY OBLIGATIONS	7

FULL PUBLIC REPORT**Polymer in Arlypon TT****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Cognis Australia Pty Ltd (ABN 87 006 374 456)
4 Saligna Drive Tullamarine, VIC 3043

NOTIFICATION CATEGORY

Self Assessment: Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Details are claimed exempt from publication. The notifier claims exemption for the Chemical Name, Other Names, Molecular Formula, Structural Formula, CAS Number, Polymer Constituents, Specific Use, Volume and Molecular weight.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Arlypon TT

INCI Name; PEG/PPG-120/10 TRIMETHYLOLPROPANE TRIOLEATE

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) >1000

The notified polymer contains no reactive 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	Off-white solid
Melting Point/Glass Transition Temp	-13 to 34°C
Density	Not determined
Water Solubility	5.07 g/L at 20°C
Dissociation Constant	No acid or base groups are present.

Particle Size	Not determined
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use. Complete combustion would yield oxides of carbon.

Comments

The notified polymer has a Closed Cup Flash Point of > 100 °C.

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>
<i>Tonnes</i>	1-3	1-3	1-3	3-10	3-10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

Import of the polymer will be as ingredient in Arlypon TT. Import will be by sea to major ports then by road or rail to customer's warehouse.

No manufacture of the notified polymer itself will occur in Australia.

The commercial form of the notified polymer will be imported in either 20 L plastic kegs or 200 L plastic lined steel drums and sold directly to customer without repacking. Storage areas will be bunded to reduce risk of environmental release.

Reformulation/manufacture processes

Blending of shampoos that will contain the notified polymer will be conducted in stainless steel blenders. The Arlypon TT would be pumped directly from the imported 200 L drums (located on scales), into the blender; typically, two such batches would be completed per day of use. The notified polymer will be blended with other shampoo ingredients, and, after quality control, the batch will be transferred via a closed system to a multi-head filling machine to consumer-type (or salon-type) containers of 250 mL, 500 mL, 1, 2, 4, or 5 L capacity). Both the blending and filling processes will be automated. The final concentration of the notified polymer in shampoos will be from 0.3 to 5%.

Use

Arlypon TT is used as a thickening agent in shampoos, especially difficult-to-thicken systems.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Worker exposure during formulation of shampoos containing the notified polymer at up to 5% will be minimised by the wearing of appropriate protective clothing including safety glasses, impervious gloves, coveralls and safety boots as well as the use of appropriate engineering controls including automated and enclosed systems. Local exhaust ventilation is expected to be present at any potential vapour or mist release points. Only in the case of end-use product package breaching, would transport, warehouse or retail workers be exposed to the notified polymer that would be present at a maximum concentration of 5%.

PUBLIC EXPOSURE

Members of the public and retail workers would be exposed only to the notified polymer at maximum concentrations of 5% when handling end-use products that contain the notified polymer. Since the notified polymer will be a minor ingredient in products sold to the general public, widespread public exposure is expected. Exposure to the notified chemical will vary depending on individual use patterns. Typically, up to 8 g of product containing from 0.5 % to 5% of the notified polymer is applied to the hair once per week. The hair is rinsed after application."

6.2. Toxicological Hazard Characterisation**Comments**

Arlypon TT, contains other ingredient/s that leads to a classification of the commercial form as a Workplace Hazardous Substance. The notified polymer is not classified as hazardous.

Based on the toxicological data on analogues noted below and the fact that the notified polymer meets the PLC criteria, the notified polymer can be considered to be of low hazard.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral (Analogue 1)	LD50 > 2000 mg/kg bw	no	no	OECD TG 401 OECD TG 423
2. Skin Irritation (Analogue 2)	Not irritating	no	no	HET-CAM *
3. Eye Irritation (Analogue 2)	Not irritating	no	no	HET-CAM
4. Mutagenicity	Not mutagenic	no	no	Ames

* Hen's egg test.

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during transfer of the imported form of the notified polymer into the end-product blender, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of Hair-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**7.1. Exposure Assessment**

ENVIRONMENTAL RELEASE

Small quantities of waste may be generated by cleaning up minor spills, cleaning out manufacturing equipment and rinsing out drums into the shampoo-blending process. Very little aqueous waste will be disposed of through the site waste treatment plant. At campaign end, the washings from factory operations are normally kept for charging into the next batch of product containing the notified polymer or other compatible products. Residues in imported drums after thorough rinsing into the blender, may contain ~0.5% and would be processed in the recycling facility's waste treatment plant, with possibly some small proportion being sent to landfill by licensed waste disposal contractors.

ENVIRONMENTAL FATE

Introduction of the imported polymer in Arlypon TT, is not expected to pose a significant risk to any organism in the environment. No instability or degradation products have been identified.

Waste model

Loss to blending factory effluent system	0.50%
Landfill from absorbing spills/leaks and maintenance jobs	0.50%
Landfill from traces left in drums isolated at drum recyclers	0.50%

Loss to blending factory effluent system	0.50%
Incinerator from drum recycling facility	0.10%
Loss to domestic sewer.	97.40%
Loss to landfill in “empty” shampoo bottles.	1.00%
Total	100.00%

7.2. Environmental Hazard Characterisation

PLCs without significant ionic functionality are of low concern to the aquatic environment.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Fish, acute toxicity (analogue 1)	LC50 > 100 mg/L		
Bacterial Toxicity (analogue 1)	EC0 > 100 mg/L		
Ready biodegradability	Not readily biodegradable	24% degraded after 28 days	OECD 301B

All results were indicative of low hazard.

7.3. Environmental Risk Assessment

As noted above, there are no scenarios that would be expected to result in significant loss to any compartment of the environment, except on disposal to sewer. The polymer will be somewhat degraded by biological action. The quantities to be used as minor ingredient in shampoos will pass to domestic sewer in a very diffuse way, indicating that no loss is likely to occur that could lead to a concentration in aqueous or soil compartment that would cause an adverse effect. The PEC in effluent is < 10 µg/L (no loss in waste treatment facility) and a risk quotient for inland rivers is acceptable (Q < 0.1) with a 1000 fold safety factor based on the above data.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

As the polymer is of high MW and of expected low toxicity and irritancy, no adverse health effects on workers carrying out blending, maintenance or clean-up operations are considered likely.

8.2. Level of Concern for Public Health

No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. 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 the commercial form and all ingredients in the formulation being prepared.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- Service personnel should wear PVC-coated cotton gloves when removing residues containing the notified polymer and during routine maintenance and repairs.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polyether 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.

Environment

- The following control measures should be implemented by re-formulation factories to minimise environmental exposure during handling of the notified polymer:
 - Open drums in a containment zone that prevents any spill or leak reaching drain or sewer.

Disposal

- The notified polymer should be recovered for re-use where possible (eg, equipment washing recycle to next product blend), or, if unrecoverable, incinerated or sent to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polyether polymer:
 - Store in a covered location that provides bunding to prevent loss to surface water or sewer.

Emergency procedures

- Spills/release of the notified polyether polymer should be handled by workers protected as recommended in the MSDS for the commercial form, Arlypon TT.

11. 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a thickening agent in shampoos, especially difficult to thicken systems, or is likely to change significantly;

- the amount of chemical being introduced has increased from 10 tonnes, or is likely to increase, significantly;
- if the chemical 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.