File No SAPLC/113

July 2010

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

# FULL PUBLIC REPORT

## POLYMER in ORGASOL CARESSE

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 Environment, Water, Heritage and the Arts 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:


| | |
|---|---|
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**Director**
**NICNAS**

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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Arkema Pty Ltd (ABN 44 000 330 772)
313 Canterbury Rd
Canterbury
Vic 3126

NOTIFICATION CATEGORY
Self Assessment: 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 formula, Structural formula, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and details of use.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Polymer of Orgasol Caresse is already listed or exempted in China, Japan, Korea, Philippines, Europe, US, Canada and New Zealand

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ORGASOL CARESSE

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (NAMW) > 1000 Da

REACTIVE FUNCTIONAL GROUPS
All the reactive functional groups have been fully reacted in the manufacture of the polymer. The notified polymer contains only low concern functional groups.

### 3. PLC CRITERIA JUSTIFICATION

| *Criterion* | *Criterion met* |
|---|---|
| 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** | White powder |
| **Melting Point/Glass Transition Temp** | > 130 °C – ISO 11357 |
| **Density** | 1.05 – ISO 1183 |
| **Water Solubility** | < 0.1% w/w. Test conducted according to Japanese standard for registration of polymers. The notified polymer is expected to have low water solubility due to its predominantly hydrophobic structure. |
| **Particle Size** | 8-12 µm ISO 13319 |
| **Reactivity** | Stable under normal environmental conditions. Not expected to hydrolyse in the environmental pH range (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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 1 | 3 | 5 | 7 | 8 |

USE AND MODE OF INTRODUCTION AND DISPOSAL

**Mode of Introduction**

The notified polymer is manufactured in Mont, France and will not be manufactured within Australia.

The notified polymer in powder form is imported in 15 kg paper bags with polyethylene liners.

It will be imported by sea through the capital cities of VIC, NSW, SA, QLD and WA.

**Reformulation/manufacture processes**

The notified polymer will not be manufactured in Australia. It will be imported and sold to cosmetic manufacturers. The notified polymer will be weighed and transferred to the batch for mixing with other ingredients to manufacture the cosmetic products.

**Use**

The notified polymer will be used as an inert texture modifier, gloss and/or lustre modifier in cosmetics at concentrations of less than 25%.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Workers may experience dermal, ocular or inhalation exposure to dust during the manufacture of the cosmetic products as Orgasol powder containing 100% of the notified polymer is weighed and added to mixing vessels, however normal good industrial hygiene such as the use of gloves, goggles and/or dust masks would minimise the exposure. After mixing with other ingredients, the concentration of the notified polymer in the finished cosmetic products will be less than 25%.

Some personal care products will be used in beauty salons where workers will come into contact with the notified polymer via dermal or ocular routes during application of the end use product.

PUBLIC EXPOSURE

The notified polymer will be present in cosmetic products at concentrations up to 25%. Dermal exposure to the notified polymer is expected to be extensive but will vary depending on individual use patterns.

### 6.2. Toxicological Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by the fact that the notified polymer has been used in cosmetics as a non active component around the world for over 10 years and there have been no reports of adverse effects during manufacture or use.

The notified polymer has a molecular weight in the range of 1,000-10,000 Da., and contains a significant portion of particles in the respirable range (< 10µm). The notified polymer is unlikely to be absorbed from the lung due to its low water solubility and molecular weight, so deposition in the lung is possible. However, it is assumed that any particulates of the notified polymer within this molecular weight range will be cleared by normal lung clearance mechanisms.

### 6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Dermal, ocular and inhalation exposure to the notified polymer is possible during reformulation into cosmetic products.

The greatest potential for inhalation exposure is expected during the manual transfer of the notified polymer (100%) in powder form into mixing vessels. The risk posed by the notified polymer upon inhalation is unknown. However, due to its molecular weight being < 10,000 Da., it is assumed that normal lung clearance mechanisms would not be overloaded following repeated inhalation of a small amount of respirable particles.

The Australian recommended exposure standard for dust is 10 mg/m$^3$ [NOHSC 3008:(1995)]. Dust levels should be minimised as much as possible during manual transfer of the notified polymer into the mixing vessels onsite. Local exhaust ventilation and/or correctly fitted respiratory protection should be worn by workers involved in manual transfer of the notified polymer to minimise inhalation exposure.

Dermal and ocular exposure is also possible during reformulation into cosmetic products. However, this is not expected to result in significant risk to the health of workers due to the anticipated low hazard of the notified polymer. Good industrial hygiene practices and the use of personal protective equipment (PPE) such as gloves, safety glasses and coveralls would also minimise the potential for exposure.

Workers in beauty salons are expected to experience dermal and possibly ocular exposure to cosmetic products containing the notified polymer at concentrations up to 25%. This is not anticipated to lead to significant risk to the health of these workers due to the anticipated low hazard of the notified polymer.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the anticipated low hazard of the polymer.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of cosmetic products, the risk to public health is not considered to be unacceptable due to the predicted low hazard of the notified polymer.

## 7. ENVIRONMENTAL IMPLICATIONS

### 7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The imported notified polymer will be reformulated into cosmetic products in Australia. During formulation a small amount of the notified polymer could be washed away during equipment cleaning. This is normally treated as site industrial waste and dealt with by licensed disposal contractors. Some will ultimately be released into the sewer. Empty import containers with any remaining residual notified polymer will be disposed of to landfill.

The formulated product will be applied to the skin. Therefore, the majority of the notified polymer is

expected to be washed off to the sewer, with the remainder disposed of to landfill as residues in product containers.

ENVIRONMENTAL FATE
The notified polymer contains groups in its backbone that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfill and eventually degrade through biotic and abiotic processes to form water vapour and oxides of carbon and nitrogen. When released to the sewer, the majority of the notified polymer is expected to be removed by up to 90% from adsorption to sludge during sewage treatment plant processes, and sludge containing the notified polymer will be disposed of to landfill or used for soil remediation. It is not likely to be readily biodegradable but, due to its high molecular weight, it is not expected to bioaccumulate.

### 7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Polymers without significant ionic functionality are of low concern to the aquatic environment.

### 7.3. Environmental Risk Assessment

Release of the notified polymer to the aquatic environment is expected to be low and dispersed as the majority of the notified polymer disposed of to sewer through wash off of cosmetic products is likely to be removed during sewage treatment plant processes. In addition, polymers without significant ionic functionality are of low concern for the environment. Notified polymer in solid wastes and sludge disposed of to landfill is likely to remain immobile and slowly degrade. Therefore, on the basis of its use pattern the notified polymer is not expected to pose a risk to the environment.

## 8. CONCLUSIONS

### 8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

### 8.2. Level of Concern for Public Health

There is 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

- Employers should implement the following safe work practices to minimise occupational exposure to the notified polymer as introduced in powder form:
  - Ensure adequate ventilation is in place to minimise dust levels.
  - The level of atmospheric dust should be maintained as low as possible. The Australian recommended exposure standard for dust is 10 mg/m$^3$ [NOHSC 3008:(1995)].

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during the application where dust

may be generated:
- Correctly fitted particle filter mask or respirator (adequate for respirable particle sizes)

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

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in resin form:
  - Avoid the formation of airborne dusts

- 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.

Disposal

- The notified polymer should be disposed of to landfill

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

## 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 component of cosmetic products, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- 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.