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January 2008

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

FULL PUBLIC REPORT

Orgasol 2001/2002/2003

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 Water Resources.

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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FULL PUBLIC REPORT**Orgasol 2001/2002/2003****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Arkema Pty Ltd (ABN 44 000 330 772)
 Ground Floor, 600 Victoria Street
 RICHMOND VIC 3121

NOTIFICATION CATEGORY

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, Polymer Constituents, Residual Monomers/Impurities, Use Details, 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)

No

NOTIFICATION IN OTHER COUNTRIES

Canada (2001)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Orgasol 2001/2002/2003

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000 Da or > 10000 Da depending on the grade

Reactive Functional Groups

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	Colourless, white powder
Melting Range	130-220°C (decomposes at > 370°C)
Density	1030-1150 kg/m ³ at 20°C
Water Solubility	8.23 × 10 ⁻³ g/L at 40°C (OECD TG 120 using total organic carbon (TOC) content measurement)
Particle Size	5 to 60 µm
Reactivity	Stable under normal environmental conditions.
Degradation Products	None under normal conditions of use. There was little change in NAMW or TOC after 1 day at pH 1.2, and 2 weeks at pH 4,7 and 9, all at 40°C.

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	1	2	3	4	5
Tonnes	10-30	10-30	10-30	10-30	10-30

Use

Approximately 60 % is used for industrial coating, 20% for cosmetics and 20% for laser sintering.

Industrial coating

The notified polymer is mixed with solvents and other components and filtered directly to drums. The coating product (containing < 10% notified polymer) is applied by professional applicators using rollers.

Cosmetics

The notified polymer is weighed and transferred to the batch for mixing with other ingredients to manufacture the cosmetic products containing less than 10% of the notified polymer, such as cosmetic pencils, eyeshadows, blushers and skin care creams. The cosmetic products will be sold to the public.

Laser sintering

This process uses a laser to fuse small particles into a mass of a particular shape. The notified polymer powder is blended with used powder and sieved into sealed containers for loading into the equipment. After the machine solidifies the powder by using lasers to melt the powder particles together in a computer-controlled process, the solid parts are removed from the machine manually. At this stage they are surrounded by a part cake of powder along with any remaining powder material. The solid models once blasted and dip sealed do not contain or hold any loose powder. Used powder is recycled.

Mode of Introduction and Disposal

The notified polymer in powder form is imported in 25 kg bag.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be assumed to have insignificant health impact. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

Endpoint	Result	Effects Observed?	Test Guideline
1. Rat, acute oral	LD50 > 5000 mg/kg bw	yes	EC Directive 79/831/EEC
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	Similar to OECD TG 402
4. Rabbit, skin irritation	non-irritating	no	Similar to OECD TG 404
5. Rabbit, eye irritation	slightly irritating	yes	Similar to OECD TG 405
6. Skin sensitisation - adjuvant test	no evidence of sensitisation.	no	OECD TG 406 (Magnusson and Kligman tests)

In the acute oral toxicity study, there was a reduced activity and lethargy after 2 to 4 hours at 5000 mg/kg bw dose level. In the eye irritation study, some minor effects were observed in conjunctiva, cornea and iris.

However the polymer contains a proportion of respirable particles and some grades are of high molecular weight (> 10000 Da). Water insoluble high molecular weight polymers used in respirable size range (< 10 µm) have the potential to cause lung overloading. No information is available on the inhalation toxicity of the polymer.

Occupational Health and Safety Risk Assessment

Industrial coating

As the polymer meets the polymer of low concern criteria and considering that workers and professional applicators will use personal protective equipment, the risk is not considered significant. However, as the notified polymer contains a significant proportion of particles in the respirable/inhalable range, workers handling the powder must have local exhaust ventilation and use respiratory protection. The risk of effects from inhalation cannot be excluded.

Cosmetics

The risk is similar to above. The critical hazard is inhalation of the powder and therefore adequate control measures will need to be in place. For professional cosmeticians and beauticians it is expected that the products will be formulated in dust free formulations and therefore the risk of inhalation is low.

Laser sintering

The risk to workers is low due to use of semi automated processes, and the engineering controls and personal protective equipment worn by workers. After the 3D digital model is formed, the notified polymer is bound with a matrix and therefore not available for exposure.

However, control measures will be needed to control manual handling of the notified polymer.

Exposure to powder of the notified polymer

The level of atmospheric nuisance dust should be maintained as low as possible. The Australian recommended exposure standard for nuisance dust is 10 mg/m³ [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

Public Health Risk Assessment

Industrial coating

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is bound within the coating film and will not be bioavailable.

Cosmetics

Since the notified polymer will be in products sold to the general public, widespread public exposure is expected. Exposure to the notified polymer will vary depending on individual use patterns. Although the public will be exposed to the notified polymer (< 10%) during use of cosmetic products, the risk to public health is not considered significant as the polymer meets the low concern criteria and it will be included in products such that significant inhalation of the powder form is not likely.

Laser sintering

The notified polymer will not be available to the public. Members of the public may make dermal contact with 3D digital models containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is bound within a matrix and not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

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

Environmental Risk Assessment

The notified polymer will not be manufactured in Australia, and therefore environmental release will not occur at this stage. Releases from reformulation may account for up to 2% of the total annual volume, arising from equipment cleaning, and residual within import containers. It is expected that the majority of this will be disposed of to landfill.

Environmental release from use in industrial coatings and in laser sintering is expected to be limited to landfill. Disposed notified polymer is expected to be associated within a stable polymer matrix and will be inert. Environmental release from use in cosmetics and from washing of rollers used in coating applications is expected to be to sewer after use. Release is expected to be diffuse across Australia with a maximum release concentration estimated to be 4.01 µg/L for these applications per annum. This is well below expected aquatic toxicity levels. The risk to the aquatic environment is therefore, considered low, based on its expected low hazard and relatively limited aquatic exposure.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

For the proposed uses and under the conditions of the occupational settings described, the notified polymer should not pose an unacceptable risk to workers or the public. The notified polymer contains particles in the respirable range. High molecular weight insoluble polymers have risk of causing lung overloading.

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in powder form:
 - Use of Local Exhaust Ventilation when handling the notified polymer in powder form
 - Avoid the formation of airborne dusts
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during certain processes where dust may be generated:
 - Use of respirator when handling notified polymer in powder form and during cleanup operations
 - Use of gloves, safety goggles and overalls
- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced in powder form
 - The level of atmospheric nuisance dust should be maintained as low as possible. The ASCC exposure standard for atmospheric dust is 10 mg/m³ but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

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 *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.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

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 polymer has changed from industrial coating, cosmetics and laser sintering, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
 - if the polymer 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.

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.