File No PLC/399

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Cromollient DP3-A

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pte Ltd (Trading as Croda Australia)
Suite A1, Ground Floor, 44-46 Mandarin Street
Villawood NSW 2163

NOTIFICATION CATEGORY
Synthetic 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
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)
No

NOTIFICATION IN OTHER COUNTRIES
No

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Cromollient DP3-A

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
Contains only non-reactive functional groups	N/A	N/A

Criterion	*Criterion met*
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not a Water Absorbing Polymer	Yes
Low Concentrations of Residual Monomers	Yes

Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10	10	10	10	10

USE
Emollient in skin moisturisers.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in 175 kg polyethylene lined steel drums and used as an ingredient in moisturiser creams and lotions at approximately 10%. The drums will be transported to a small number of formulation sites in Australia. At the formulation sites the contents of the drums will be stirred before the polymer is manually weighed into smaller containers under exhaust ventilation. The weighed polymer will then be added to sealed mixing tanks and blended with water and other ingredients at approximately 70^0C to make skin moisturiser creams and lotions. After cooling to 40^0C, the moisturiser formulations will be piped directly to automatic filling machines, and filled into consumer packages, to be sold to the public through retail outlets. Sampling and testing of the notified polymer and moisturiser formulations will be carried out as part of quality control.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

During the formulation of moisturiser creams the estimated annual losses of notified polymer are:

Spill and Equipment cleaning	50 kg
Import container residuals	30 kg
Total Annual Loss	80 kg

The majority of the notified polymer will be incorporated into the moisturisers and will be released to the environment during washing. Approximately 2% of the end product will remain in the empty end-use container, this equates to less than 200 kg of notified polymer annually.

Fate

Any spilt material and the import container linings with any residual material will go to landfill. The effluent, containing any notified polymer, generated during equipment cleaning will go to on site treatment plants and will then be released to trade waste after treatment and removal of solids. The solids will be sent to landfill.

The moisturiser will be washed down the drain thus releasing the majority of the notified polymer to sewer. The end-user container, containing any residual material will be disposed into general rubbish, which goes to landfill. While the notified polymer contains groups which are potentially hydrolysable, this is not expected to occur in the environmental pH range of 4-9. In sediment/landfill it may be anticipated that the polymer will slowly degrade.

The notified polymer is not expected to be soluble in water and as such is not expected to be mobile in

either the aquatic or terrestrial compartments. Residual chemical disposed of into landfill within empty containers or in spill clean-up material, is not expected to leach from landfill.

6.2. Summary of Occupational Exposure

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Dermal and ocular exposure can occur during formulation, QC and filling processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

6.3. Summary of Public Exposure

Skin moisturising creams and lotions containing up to approximately 10% of the notified polymer will be sold to the general public. Members of the public will therefore make dermal contact and possibly accidental ocular contact with products containing the notified polymer. The moisturiser will be applied and rubbed into the skin, and is likely to be used once or twice daily. Depending on whether the moisturiser is designed for use on the face, hands or whole of the body, the amount used in one application is estimated to be 0.8 g to 8.0 g, containing approximately 0.08 to 0.8 g of the notified polymer. Based on these figures the daily dermal contact with the notified polymer will range from 0.08 g to 1.6 g. However, exposure will be low because the notified polymer has a high molecular weight (NAMW > 1000) and would not be expected to pass through the skin.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Colourless to pale yellow oily liquid.
Melting Point	Information not supplied. Liquid at 25ºC
Density	Information not supplied.
Water Solubility	Insoluble in water – due to its hydrophobic constituents
Dissociation Constant	Information not supplied. The notified polymer does not contain any functional groups which would be expected to dissociate under environmental conditions (pH 4-9).
Particle Size	Not applicable
Reactivity	Stable under normal environmental conditions
Degradation Products	Oxides of carbon

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological studies were submitted:

Endpoint	*Result*	*Classified?*	*Effects Observed?*
In vitro skin irritation (Epiderm)	non-irritating	no	no
Skin sensitisation – Human repeat insult patch test (RIPT)	no evidence of sensitisation.	no	no
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no

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

As no data are available it is not possible to characterise aquatic toxicity. However, polynonionic polymers which have a NAMW > 1000 are of low concern.

10. RISK ASSESSMENT

10.1. Environment

Based on annual imports of 10,000 kg per annum of the notified polymer, and assuming the majority 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	10 000 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365
PEC_{sewer}	$\frac{10\,000\,000\,000 \text{ mg}}{20\,000\,000 \times 200 \times 365 \text{ L}}$
	= 0.0068 mg/L
	= 6.8 µg/L

When released to receiving waters (ocean) the concentration is generally understood to be reduced by a further factor of at least 10. However, as the moisturiser 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.

Since no ecotoxicological data were provided a hazard quotient (HQ = PEC/PNEC) cannot be calculated. However, based on the proposed use pattern of the notified polymer, the amount being imported, the nationwide use of the moisturiser products and subsequent diffuse release and its expected low toxicity it is not expected to pose an unacceptable risk to aquatic life.

It is unlikely that the new polymer will present a risk to the environment when handled and used as indicated. Hence, environmental risk from the proposed use is expected to be low.

10.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low.

10.3. Public health

The risk to the public is expected to be low for the proposed method of use in skin moisturisers, based on the low bioavailability of the notified polymer, which has a NAMW > 1000.

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 skin moisturiser ingredient.

12. MATERIAL SAFETY DATA SHEET

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 moisturiser product manufacturer to minimise environmental exposure during end product formulation of the notified polymer:
  – Process areas to be bunded;
  – Storm drains should not be within processor storage areas, to avoid any of the notified polymer entering the storm drains.

Disposal

- The notified polymer should be disposed of by landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment with absorbent material, collection and storage in sealable labelled container.

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.
  – the notified polymer is introduced in a form where NAMW is < 1000.

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.