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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Cromollient SCE

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Cromollient SCE

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pte Ltd (Trading as Croda Australia)

NOTIFICATION CATEGORY
Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity details.

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
None known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Cromollient SCE

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
No reactive groups		N/A

Criterion	*Criterion met (yes/no/not applicable)*
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	N/A
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 body washes, liquid soaps, facial cleansers and shampoos (particularly baby shampoos).

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in 175 kg drums and transported first to the notifier's warehouse and then to formulation sites. During formulation into cosmetic cleansing products, the contents of the drums will be mechanically stirred, and the notified polymer will be manually weighed into smaller containers before transfer to a sealed blending tank. After mixing with other ingredients at approximately 70^0C the final cleanser product will be cooled to 40^0C and piped directly to automatic filling machines. It will be filled into consumer packages, for distribution to the public. Sampling and testing of the notified polymer and cleanser formulations will be carried out as part of quality control.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

Manufacture and Reformulation

The notified polymer will be imported for reformulation, at a small number of sites in Australia. Release volumes from reformulation are expected to be low, with estimates of up to 100 kg/annum from residues remaining in drums after emptying, and up to 100 kg/annum from spills during reformulation and from cleaning of equipment. All wastes resulting from reformulation will be treated in an on-site treatment plant, where they will be neutralised and solids removed for landfill and the liquid effluent discharged to trade waste.

Use

The end products containing the notified polymer will be widely distributed and used throughout Australia. The notified polymer will be used in a range of cosmetic products that will mainly be washed off to sewer following use. At least 90% of the bodywashes, liquid soaps and facial cleansers and shampoos containing the notified polymer will be washed off. The end use containers are expected to be disposed of with normal household garbage to landfill and recycling processes. The residues of the notified polymer remaining in these containers are expected to be 2% or up to 200 kg/annum

The notified polymer is immiscible in water and therefore unlikely to be mobile in the aquatic and terrestrial compartments of the environment. When released to sewer and landfill, as a consequence of its low miscibility, the notified polymer is expected to have a high affinity with the sludge, soil and sediment, and shouldn't hydrolyse despite the presence of hydrolysable groups.

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 certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and 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 shampoos or skin cleansers to clients, and such exposure would be greatly reduced by use of gloves.

6.3. Summary of Public Exposure

The notified polymer is an emollient that will be used at 10% in body washes, liquid soaps, facial cleansers and shampoos (particularly baby shampoos). These cosmetic products containing the notified polymer are for sale to the general public, and some may be applied to the public at hairdressing or beauty salons.

Members of the public including babies and children will make dermal contact and possibly accidental ocular contact with cleansing products containing the notified polymer.

The exposure scenario involving use of shampoo on very young babies would lead to relatively high potential dermal exposure – estimated at 130 mg/kg bw/day for daily use of 4g shampoo containing 10% of the notified polymer on a 3 kg baby. Other scenarios would produce lower exposure eg use of 8 g/day of the same shampoo by a 60 kg adult would lead to potential dermal exposure of 13 mg/kg bw/day.

Actual exposure would be reduced from this figure because most of the shampoo would be washed off after brief contact. Exposure would also be reduced because skin absorption would be limited by the high molecular weight (NAMW > 1000). Analyses did not clearly characterise the proportion of molecular weight species >1000, which are <20% but may be close to zero.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Clear pale yellow oily liquid
Melting Point/Glass Transition Temp	Not supplied. Liquid at 25ºC
Density	Specific gravity 1.0.
Water Solubility	Described as being insoluble in water, but it is dispersible in water and can be emulsified with surfactants. Solubility determined in a qualitative manner. Insoluble in water and 75:25 water:ethanol but soluble in 50:50 water:ethanol solution. This appears to reflect the presence of groups which are likely to confer greater polarity.
Dissociation Constant	The notified polymer does not contain any functional groups which would be expected to dissociate under environmental conditions (pH 4-9).
Reactivity	Stable under normal environmental conditions. May react with strong oxidising agents.
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)	Very mild to non-irritating	no	no
Skin sensitisation – Human repeat insult patch test (RIPT)	no evidence of irritation 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 ecotoxicological 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 MW > 1000 are of low concern.

10. RISK ASSESSMENT

10.1. Environment

The notified polymer will be used in body washes and therefore result in the eventual release of almost the entire import volume to the aquatic environment from use. Based on annual imported volume of 10 tonnes and assuming at least 90% is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 24.6 kg/day. The predicted concentrations in sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer annually (V)	9000 kg
Population of Australia (P)	20 million
Amount of water used per person per day (W)	200 L
Number of days in a year (D)	365
Estimated $PEC_{aquatic}$ (Ocean)	0.61µg/L
Estimated $PEC_{aquatic}$ (River) (V/[P x W x D])	6.1 µg/L

Since no ecotoxicological data were provided a risk quotient (RQ = PEC/PNEC) cannot be calculated. However, based on the proposed use pattern of the notified polymer, the nationwide use of the body wash 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, if used with appropriate controls. For formulation processes this would comprise engineering controls and PPE. On the basis of in vitro testing the potential for skin irritation is low, however repeated contact could be irritating to the skin. Use of gloves by hairdressers and beauticians while applying cleansing products would protect against skin irritation.

10.3. Public health

The risk to the public is expected to be low for the proposed applications in personal cleansers, based on the low dermal contact time for wash-off products and the low bioavailability of the notified polymer, which has a NAMW > 1000. However it should be noted that the calculated potential exposure to young children is relatively high, and the percentage of species of molecular weight > 1000 has not been fully characterised.

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 personal cleansers.

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

- Where needed, personal protective equipment, engineering controls and safe work practices should be used to protect workers against exposure to the notified polymer or products containing it:
  - 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 the 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 containers.

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 used at >10% in personal products that are left on the skin;

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.