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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Aristoflex PEA 70

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd, 675 Warrigal Road, Chadstone, VIC, 3148

and

Johnson and Johnson Pacific, Level 3, 1 Bay St, Broadway, NSW, 2007

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)
Yes, LVC583

NOTIFICATION IN OTHER COUNTRIES
USA, PMN=P86-113

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Aristoflex PEA, Polymer in Aristoflex PEA 70 (70% aqueous solution of Aristoflex PEA)

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
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 Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard 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	2	2	2	2	2

USE

The notified polymer will be incorporated at low levels in a range of bodywashes, as a skin conditioning agent.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported to either Sydney or Melbourne as a component of a range of bodywashes for retail sale in Australia. The bodywash is packaged in 250 mL and 400 mL containers. It will not be manufactured, reformulated or repackaged in Australia. The work will involve handling of the products either in their retail packaging or in outer cartons. The product is to be distributed to retail outlets throughout Australia.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

Use

It is assumed that 1-2% residue will occur in emptied containers, which will be disposed of via domestic waste to land fill and recycling processes.

The notified polymer will be used in a range of cosmetic products containing 2000 kg/annum of the notified polymer that will mainly be washed off to sewer following use.

The notified polymer is fully miscible in water and as such is likely to be mobile in the aquatic and terrestrial compartments of the environment. When released to sewer and landfill, as a consequence of its high miscibility, the notified polymer is not expected to have a high affinity with the sludge, soil and sediment.

6.2. Summary of Occupational Exposure

Category of worker	Number	Exposure Duration (hours per day)	Exposure Frequency (days per year)
Quality Assurance Engineer	1	2	3
Transport & Storage	4	<1hr/day	
Retail Workers			

During transport, storage and handling, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Even in the event of an accident, little exposure is expected due to the low concentration of the notified polymer in the product and the small package sizes.

6.3. Summary of Public Exposure

Cosmetic products containing the notified polymer are for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low due to the small amounts used per application, the pattern of use and the low concentration of the notified polymer in the product.

7. PHYSICAL AND CHEMICAL PROPERTIES

Physical and chemical property data were available for both the notified polymer Aristoflex PEA, and its 70% aqueous solution Aristoflex PEA 70.

	Aristoflex PEA	Aristoflex PEA 70
Appearance at 20°C and 101.3 kPa	Amber Solid Wax	Transparent amber liquid
Melting Point	31-37 °C	
Density	1125 kg/m^3 at 50°C	1100 kg/m^3 at 50°C
Water Solubility	Miscible at 20°C	Soluble at 70%
Reactivity	Thermal decomposition occurs at 350° C. At all pH values from 3-8, the notified polymer is stable in 5 % aqueous solution over a period of 4 weeks at room temperature and at 45° C.	At pH 9, after 5 days at 50° C the notified polymer shows a significant decrease in the higher molecular weight components (by HPLC) and a strong increase in peak intensity in the low molecular weight region. It has been concluded that the polymer is not stable in alkaline solution.
Degradation Products	Oxides of carbon	

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological studies were submitted for Aristoflex PEA

Endpoint	*Result*	*Classified?*	*Effects Observed?*
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	yes
2. Rabbit, skin irritation	non-irritating	no	no
3. Rabbit, eye irritation	non-irritating	no	yes
6. Skin sensitisation – Buehler Test	no evidence of sensitisation.	no	no
8. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no

All results were indicative of low hazard.

8.1.1 Discussion of Observed Effects

Rat, acute oral

All ten animals treated showed hunched posture, lethargy, pilo-erection and a decreased respiratory rate one hour after dosing. Hunched posture and pilo-erection persisted in all animals four hours after dosing. All animals had recovered and appeared normal on day one and for the remainder of the study.

Rabbit, eye irritation

Minimal conjunctival redness was noted in all treated eyes one hour after treatment. All treated eyes were normal at subsequent 24, 48 and 72 hour observations.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. Although not classified as an eye irritant, minimal short term eye irritation could occur upon contact.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The toxicity of the notified polymer towards zebra fish was measured according to OECD 203 with a reported LC50 of 79 mg/L (96 h).

The toxicity of the notified polymer towards bacteria was measured according to OECD 209 with a reported EC50 of 5.1 g/L. No test report provided.

Biodegradability of the notified chemical was measured according to the tests OECD 301 B and OECD 302B, and was found to be 79% (28 days) and 95% (17 days) respectively. No test report provided.

9.1.1 Discussion of Observed Effects

Fish toxicity

The toxicity of the notified polymer to zebra fish (*Danio rerio*) was measured by exposing zebra fish (7 fish were used per test concentration and control) to five nominal concentrations up to 100 mg/L and a control, at 23±2°C, 16-h light photoperiod, dissolved oxygen at not less than 60% of air saturation value and pH 6.0-8.5. After 96 h duration, the LC50 was 79 mg/L (58-100 mg/L), the NOEC was 50 mg/L. This is based on one dead fish at 25 and 50 mg/L (not considered biologically significant), but 2 deaths after 24 h and 5 deaths after 96 h at 100 mg/L.

9.2. Environmental Hazard Assessment

No test reports were included for biodegradability or toxicity towards bacteria, and based on the test report data for zebra fish the notified polymer is toxic to fish. Polynonionic polymers which have MW > 1000 are generally of low concern.

10. RISK ASSESSMENT

10.1. Environment

The notified polymer will be used in bodywashes and, as such, will result in the eventual release of most of the import volume to the aquatic environment from use. Based on annual imported volume of 1600 kg (2000 kg imported, however 20% re-exported to New Zealand), and assuming the majority 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 4.4 kg/day. The predicted concentrations in sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer annually (V)	1600 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)	0.11 μg/L
Estimated $PEC_{aquatic}$ (River) (V/[P x W x D])	1.1 μg/L

Aquatic toxicity data claimed by the notifier for fish were (LC50 of 79 mg/L). Using a safety factor of 1000 to account for the lack of toxicity data from more than one aquatic taxa, the predicted no effect concentration (PNEC) for the notified polymer for the protection of aquatic ecosystems is 79 μg/L. The worst case PEC/PNEC ratios for the aquatic environment if the notified polymer is used nation wide when released to ocean and inland rivers are 0.001 and 0.01, respectively. These values are significantly less than 1, indicating low concern to the aquatic compartment. During wastewater treatment procedures, some attenuation of the notified polymer is expected.

The notified polymer is not likely to present a risk to the environment when it is transported and used in the proposed manner.

10.2. Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low due to lack of direct contact except in the event of an accident, the low concentration of the notified polymer in the handled product and the low hazards associated with the notified polymer.

10.3. Public health

The public will become exposed to the notified polymer through use of the bodywashes. However, the risk to the public from exposure to the notified polymer is considered low due to the low toxicity of the notified polymer, the small amounts used per application, the pattern of use and the low concentration of the notified polymer in the product. At the low concentrations present in the final product and due to the pattern of use, the notified polymer is not expected to cause eye irritation.

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 No Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2 Public health

There is Negligible Concern to public health based on its reported use pattern.

12. MATERIAL SAFETY DATA SHEET

Material Safety Data Sheet

The notifier has provided MSDS for the imported product 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

- A copy of the MSDS should be easily accessible to employees.

Environment

Disposal

- Recycle whenever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.

Emergency procedures

- Spills/release of the notified polymer should be prevented from entering waterways and be contained with sand or vermiculite. The recoverable product should be collected into labelled containers for recycling and the remainder should be absorbed with sand, earth, or vermiculite and placed in appropriate containers for disposal.

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.

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.