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

FULL PUBLIC REPORT

Aristoflex AVC

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Aristoflex AVC****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)
Warrigal Road
CHADSTONE VIC 3148

Trimex Pty Ltd

5 Crewe Place
ROSEBERY NSW 2018

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
- 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)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Aristoflex AVC
Clarins Men Moisture Gel

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
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
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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<5	<5	<5	<5	<5

USE

The notified polymer will be used as a gelling agent for aqueous systems and as a texturiser, thickener for oil-in-water emulsions. For example, it will be used in a moisture gel.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in finished cosmetic products at a concentration of 0.5-1.2% in consumer sized packages (e.g. 50 mL) or as the polymer product Aristoflex AVC in 200 kg drums.

Imported cosmetic products containing the notified polymer will be transported to the notifier's warehouse for interim storage prior to distribution to customers.

Where the notified polymer is imported neat, it will be transported either to the notifier's warehouse or into end-user stores (as yet undetermined).

Reformulation of the notified polymer will only be carried out by end-user companies manufacturing cosmetic products. At these sites, drums of Aristoflex AVC are moved from storage to the dispensing area where the notified polymer is dispensed into smaller sealable plastic tubs and then manually transferred to the manufacturing vessel with the balance of ingredients for the formulation of the final product.

The concentration of the notified polymer in the final product will range from 0.5-1.2% depending on the product being manufactured.

The final formulation is then pumped into a sealed holding tank which is then transferred to the packaging floor via pallet trolley. The product is transferred to an automated filling line from the sealed holding tank via a circuit of pipes and pumps. Following manufacture and packaging the empty holding tank is washed and the vessel is steam cleaned and stored for further use.

The packaged product is then distributed for use throughout Australia.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

Import

Environmental release of the notified polymer is unlikely during importation, storage and transportation, with spillage during a transport accident the most likely reason for environmental release. Individual container capacity and container specifications would limit the extent of release.

Aristoflex AVC will be imported packaged in 200 kg polyethylene drums. Approximately <3 kg per annum of the notified polymer may potentially remain in emptied drums, with drum contents rinsed and sent to on-site wastewater treatment plant (WWTP), probably with sewer disposal of treated

effluent. Cleaned drums will be recycled.

Manufacturing

Approximately 50-100 batches of product will be manufactured in Australia in up to 10 product types. During the formulation batch process, cleaning of batching equipment may potentially generate 2.5 kg/batch of waste manufactured product containing diluted notified polymer per batch (250 kg product/annum containing <3 kg notified polymer) for discharge to on-site WWTP (treatment capacity 10000 L/treatment cycle), which discharges to Melbourne Water's sewerage system.

Use

End products containing the notified polymer will be widely distributed and used throughout Australia. Types of containers will include 50, 120 and 250 mL plastic bottles. Approximately <5% of the notified polymer will remain in emptied containers, which will be discarded to landfill or recycled through plastic bottle recycling programs.

The notified polymer will be used in a range of cosmetic products containing <5000 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. Based on its low ready biodegradability test results (7% degradation in 28 days), the notified polymer is likely to slowly degrade through the abiotic and biotic processes to water and oxides of carbon and nitrogen. Incineration of the notified polymer will produce water and oxides of carbon and nitrogen.

6.2. Summary of Occupational Exposure

Manufacture

- Incidental skin and ocular contact with the powdered notified polymer may occur during weighing and dispensing into plastic tubs for batch addition. Inhalation exposure to dust is also possible, however, the dispensary is fitted with a dust-extraction system at the weighing station.
- Laboratory technicians may be exposed dermally and ocularly to small amounts of the neat polymer and the final product during sampling and quality control testing.
- Post-formulation dermal and ocular exposure may occur during the transfer of the product to the holding tank through disconnection of hoses and pump equipment.
- Packaging of the cosmetic product is a highly automated process and exposure is not expected except in the event of leaking or malfunctioning filling equipment or transfer lines.
- Workers are expected to wear gloves, protective clothing and eye protection during these operations.

Transport & Storage

- Exposure to either the neat polymer Aristoflex AVC or the final cosmetic product containing 0.5-1.2% notified polymer is not expected to occur during transport and storage except in the event of an accident where the packaging may be breached.

Retail

- Retail workers involved in the shelf filling and sale of the final consumer product are not expected to be exposed to the notified polymer except in cases of an accident where the packaging may be breached

End-Use

- Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE (1997) modelling of this work environment, exposure in the range of 1-5 mg/cm²/day of products containing up to 0.5-1.2% of the notified polymer could result. Dermal exposure is expected during application of certain products and accidental ocular exposure may also occur. The notified polymer is non-volatile, however, if it is present in product applied as a mist or aerosol, inadvertent inhalation of the notified polymer may also occur.

6.3. Summary of Public Exposure

Cosmetic products containing the notified polymer at concentrations of up to 1.2% 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. In most cases exposure is expected to be limited to 1-10 grams of product, 1-2 times per day.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White powder
Melting Point/Glass Transition Temp	Decomposition at >250°C
Density	230 kg/m ³
Water Solubility	>5 g/L at 20°C Fully miscible with water (Clariant GmbH, 1995). OECD TG 105. 20±0.5 °C. A range of dilutions (1000 g/L to 5 g/L) gave homogenous solutions, with the highest concentration showing clear gel without particles or phase separation (measured by observations of turbidity, clarity, etc. from a series of dilutions).
Hydrolysis as a function of pH	Hydrolytically stable at environmentally relevant pH conditions. The hydrolysis of the polymer was tested according to OECD TG 111. The change in molecular weight after 24 h at 50°C and pH 1.2, as well as pH 4.0, 7.0 and 9.0 was less than 10%. Therefore the polymer is considered hydrolytically stable. Prolonged storage at pH <4.0 may lead to acid cleavage. pH higher than 9.0 may result in release of ammonia (Clariant, 1981).
Particle Size	> 2000 µm : 0% < 2000 µm : 97.2% < 1000 µm : 81.3% < 200 µm : 11.8% < 100 µm : 0.5%
Reactivity	Stable under normal environmental conditions. May release ammonia under alkaline conditions.
Degradation Products	No degradation expected

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological information was provided by the notifier and is based on studies on an analogue polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral (OECD 401)	LD50 > 2000 mg/kg bw (Hoechst, 1996a).	No	Not stated
Rabbit, skin irritation (OECD 404)	non-irritating (Hoechst, 1996b).	No	Not stated
Rabbit, eye irritation (OECD 405)	slightly irritating (Hoechst, 1996c).	No	Slight Irritation
Skin sensitisation (OECD 406)	no evidence of sensitisation. (Hoechst, 1996d).	No	Not stated
Genotoxicity - bacterial reverse mutation (OECD 471)	non-mutagenic (Hoechst, 1996e).	No	Not stated

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. The powder may cause irritation to the eyes and repeated or prolonged skin contact may result in mild irritation. A small fraction of the polymer particles are in the inspirable range and mechanical irritation to the respiratory tract may occur if inhaled.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following toxicological information was provided by the notifier and is based on studies on an analogue polymer.

<i>Endpoint</i>	<i>Result and Conclusion</i>
Ready Biodegradability	Not biodegradable (Dr. U. Noack-Laboratorium, 1999b)
Fish Toxicity	EC50 >327 mg/L (measured conc.) (Hoechst, 1996)
Inhibition of Bacterial Respiration	EC50 >3200 mg/L (Dr. U. Noack-Laboratorium, 1999a)

9.1.1 Discussion of Observed Effects

Fish toxicity

The toxicity of the analogue polymer to zebrafish (*brachydanio rerio*; 2.7-3.0 cm body length) was measured according to OECD TG 92/69/EWG by exposing fish (7 fish per treatment) to one concentration (327 mg/L measured; 1000 mg/L nominal) and a control at 22±1°C, 16-h light photoperiod, dissolved oxygen 6.9-9.9 mg/L and pH 7.6-8.2. After 96 h, no mortality or sublethal effects were observed giving a NOEC of 327 mg/L and a 96 h LC50 of >327 mg/L.

Ready biodegradability

The analogue polymer (30 mg/L) was incubated with activated sludge from a municipal waste treatment facility in Germany in the dark at 22±2°C for up to 28 d according to OECD TG 301B/CO₂ Evolution Test for Testing of Chemicals. After 28 d, the loss of oxygen indicated that only 7% biodegradation occurred which is less than the 60% required to classify the notified polymer as readily biodegradable. Therefore, under the conditions of the test, the analogue polymer was not readily biodegradable.

10. RISK ASSESSMENT

10.1. Environment

The notified polymer will be used in cosmetics and, therefore will result in the eventual release of most of the polymer to the aquatic environment from use. Based on annual imports of <5000 kg, and assuming that the majority of this 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 <13.7 kg/day. The predicted concentrations in sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer annually	<5000 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC _{aquatic} (Ocean)	0.3 µg/L
Estimated PEC _{aquatic} (River)	3 µg/L

Aquatic toxicity data were available for fish, with no effects to fish identified at the highest concentration tested (ie. 96 h LC50 >327 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 327 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 river are 0.001 and 0.01, respectively. These values are significantly less than 1, indicating no immediate 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 stored, transported and used in the proposed manner.

10.2. Occupational health and safety

Worker exposure to the notified polymer during transport and storage of either Aristoflex AVC or finished products is only possible in the event of an accidental spillage.

The notified polymer is may be irritating eye and skin with prolonged contact, however, the notified polymer is not hazardous and worker exposure is limited by engineering controls such as dust extraction, sealed reaction vessels and automated packaging processes. Personal protective equipment worn by workers during manufacture and end-use will further reduce the risk of irritation.

Therefore, the OHS risk presented by the notified polymer during transport, storage, and reformulation is expected to be low due to its expected low hazard and low potential for worker exposure.

Potential for occupational exposure occurs in those professions, such as hairdressing and beauty therapy, where workers may apply cosmetic products containing the notified polymer several times each working day. Dermal exposure is the main route of exposure although inadvertent ocular exposure may also occur. However, the notified polymer is of low hazard, high molecular weight, and present in low concentrations, therefore the risk to these workers is considered low.

10.3. Public health

The products containing the notified polymer will be used by the general public applying the products themselves, and also by those having products applied during professional hairdressing or cosmetic applications. The notified polymer has a MW > 1000, and thus will be unable to cross biological membranes. Despite the potential widespread use, the risk to public health is considered low due to the non-hazardous nature of the notified polymer.

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 and PEC/PNEC ratio.

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 the intended manner.

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

- 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* (NOHSC2002), workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of by incineration or landfill in accordance with State/Territory waste management regulations. Product containing the notified polymer should be disposed of to sewer.

Emergency procedures

- Spills/release of the notified polymer should be handled by sweeping and placing spilled powder in sealed container for disposal. Do not allow entry to stormwater drains or waterways.

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.

References

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Hoechst (1996a). Poly AMPS Testing for acute oral toxicity in the male and female Wistar Rat. Hoechst AG, Germany. Report no. 96.0401. 19 pp.

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Hoechst (1996c). Poly AMPS Test for primary eye irritation in the rabbit. Hoechst AG, Germany. Report no. 96.0261. 18 pp.

Hoechst (1996d). Poly AMPS Testing for the sensitising properties in the Pirbright-White guinea pig according to the method of BUEHLER. Hoechst AG, Germany. Report no. 96.0521. 19 pp.

Hoechst (1996e). Poly AMPS Bacterial Reverse Mutation Test. Hoechst AG, Germany. Report no. 96.0358. 34 pp.

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