

File No PLC/473

10 September 2004

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

FULL PUBLIC REPORT

Aristoflex AVC

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 Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
National Occupational Health and Safety Commission
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is 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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION.....	5
5. PROCESS AND RELEASE INFORMATION.....	5
5.1. Operation Description.....	5
6. EXPOSURE INFORMATION	5
6.1. Summary of Environmental Exposure.....	5
6.2. Summary of Occupational Exposure	5
6.3. Summary of Public Exposure	6
7. PHYSICAL AND CHEMICAL PROPERTIES.....	6
8. HUMAN HEALTH IMPLICATIONS.....	6
8.1. Toxicology.....	6
8.2. Human Health Hazard Assessment.....	7
9. ENVIRONMENTAL HAZARDS.....	7
9.1. Ecotoxicology	7
9.1.1 Discussion of Observed Effects	7
10. RISK ASSESSMENT.....	7
10.1. Environment	7
10.2. Occupational health and safety	8
10.3. Public health	8
11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS.....	8
11.1. Environmental risk assessment	8
11.2. Human health risk assessment	8
11.2.1. Occupational health and safety.....	8
11.2.2 Public health.....	8
12. MATERIAL SAFETY DATA SHEET	8
Material Safety Data Sheet.....	8
13. RECOMMENDATIONS.....	9
13.1. Secondary notification	9
14. REFERENCES	9

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

Unilever Australasia Pty Ltd (ABN 66 004 050 828)
 219 North Rocks Road
 NORTH ROCKS NSW 2151

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.

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Aristoflex AVC

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>	0.15	0.3	0.3	0.3	0.3

USE

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

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will be imported in finished cosmetic products at a concentration of <5% in consumer sized packages (e.g. 50 mL).

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

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.

Use

End products containing the notified polymer will be widely distributed and used throughout Australia. Types of containers will include 50 and 120 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 <1000 kg/annum of the notified polymer that will mostly be washed off to the sewer.

The notified polymer is fully miscible in water and as such is likely to be mobile in the aquatic and terrestrial environments. When released to the 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 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

Transport & Storage

- Exposure to the final cosmetic product containing <5% 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 cosmeticians and beauticians. According to EASE modelling of this work environment, exposure in the range of 1.5 mg/cm²/day of products containing up to <5% 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 <5% 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 homogeneous 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 the studies on an analogue polymer.

Endpoint	Result and Conclusion
Ready Biodegradability	Not biodegradable (Dr. U. Noack-Laboratorium, 1999b)
Fish Toxicity	EC50 > 327 mg/L (measured conc.) (Hoechst, 1996f)
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 days according to OECD TG 301B/CO₂ Evolution Test for Testing of chemicals. After 28 days, 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 <1000 kg, and assuming that the majority of this will eventually be released to the sewer and is not removed during the sewage treatment process, the daily release on a national wide basis to receiving waters is estimated to be <2.7 kg/day. The predicted concentrations in the sewage effluent on a nationwide basis are estimated to be:

Amount entering sewer	<1000 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 (Ocean)	0.07 µg/L
Estimated PEC (River)	0.7 µg/L

Aquatic toxicity data for an analogue polymer 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 in toxicity data from more than one aquatic taxa, the predicted no effect concentration (PNEC) for the notified polymer 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 0.0002 and 0.002, 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 a proper manner.

10.2. Occupational health and safety

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

The notified polymer may be irritating eye and skin with prolonged contact, however, the notified polymer is not classified as a hazardous substance.

Therefore, the OHS risk presented by the notified polymer during transport and storage 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 NAMW > 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

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 a 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.

14. REFERENCES

Clariant GmbH (1981). Aristoflex AVC. Hydrolysis as a function of pH. Clariant GmbH, Frankfurt. H 728-2.

Clariant GmbH (1995). Aristoflex AVC. Water Solubility. Clariant GmbH, Frankfurt. Report no. H 728-1.

Dr. U. Noack-Laboratorium (1999a). <notified chemical>. Respiration Inhibition Test with Activated Sludge. Germany. Report No. BBR52781.

Dr. U. Noack-Laboratorium (1999b). <notified chemical>. Ready Biodegradability, Modified Sturmtest. Germany. Report No. AST52781.

EASE for Windows (1997) Version 2.0; Health and Safety Executive, UK.

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

Hoechst (1996b). <notified chemical> for primary dermal irritation in the rabbit. Hoechst AG, Germany. Report no. 96.0260. 14 pp.

Hoechst (1996c). <notified chemical> Test for primary eye irritation in the rabbit. Hoechst AG, Germany. Report no. 96.0261. 18 pp.

Hoechst (1996d). <notified chemical> 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). <notified chemical> Bacterial Reverse Mutation Test. Hoechst AG, Germany. Report no. 96.0358. 34 pp.

Hoechst (1996f). <notified chemical> 96-hour acute toxicity study in zebra fish (*Brachydanio rerio*). Hoechst AG, Germany. Report no. 96.0406. 20 pp.

NOHSC (2002). Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, AusInfo.