File No PLC/1340

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Aristoflex AVS (INCI name: Sodium Acryloyldimethyltaurate/VP Crosspolymer)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment and Energy.

This 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:

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Director
NICNAS

October 2016

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1340	Clariant (Australia) Pty Ltd	Aristoflex AVS (INCI name: Sodium Acryloyldimethyltaurate/VP Crosspolymer)	No	≤ 1 tonne per annum	Component of cosmetics

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer when introduced in powder form:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid inhalation of dusts
  - The level of atmospheric dust should be maintained as low as possible. The Australian recommended exposure standard for dust is 10 mg/m^3 [NOHSC 3008:(1995)].

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 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 Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from component of cosmetics, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Level 3, 3 Acacia Place
296-324 Ferntree Gully Road
Notting Hill VIC 3168

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, spectral data, use details, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Aristoflex AVS

Other Name(s)
Sodium Acryloyldimethyltaurate/VP Crosspolymer (INCI name)

Molecular Weight
Number Average Molecular Weight (Mn) is > 10,000 Da

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	White powder
Melting Point/Glass Transition Temp	Not determined; decomposes prior to melting
Density	Not determined
Water Solubility	Miscible, gel forming*
Dissociation Constant	pKa = 1.7 ± 0.5
Particle Size	Fraction < 10 µm – 65.4% Fraction < 100 µm – 86.8%
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*When the gel was diluted by addition of further water, a low viscosity solution was formed.

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 0.5	< 1	< 1	< 1

Use
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as a powder for reformulation into cosmetics in 25 kg fibreboard boxes with a sealed inner polyethylene bag. Finished cosmetics containing < 5% notified polymer will be sold to the public in 250 mL to 5 L plastic bottles.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints for the notified polymer or an analogue polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral (analogue)	LD50 > 2000 mg/kg bw	yes*	OECD TG 401
Rabbit, skin irritation (analogue)	non-irritating	no	OECD TG 404
Rabbit, eye irritation (notified polymer)	slightly irritating	yes**	OECD TG 405
Skin sensitisation – LLNA (notified polymer)	no evidence of sensitisation	no	OECD TG 429
Genotoxicity – bacterial reverse mutation (notified polymer)	non mutagenic	no	OECD TG 471

*Clinical signs noted were irregular respiration, respiration sounds, squatting posture and swollen abdomen. All effects had resolved by Day 4 after dosing.
** Slight conjunctival effects which resolved by 24 h.

The notified polymer is of high molecular weight > 10,000 Da and particle size information indicates that a significant portion will be respirable (< 10 μm). The notified polymer is water soluble and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The expected use of dust masks and local exhaust ventilation when handling the powdered notified polymer by reformulation workers should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers and/or impurities that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

The results from ecotoxicological investigations in fish and algae conducted on the notified polymer were submitted. Based on the ecotoxicological endpoints for the notified polymer, it is not expected to be harmful to aquatic organisms. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, the notified polymer is not formally classified for acute and chronic toxicities. The actual concentrations of the notified polymer in the test media were not determined as no effects were observed at the highest concentrations tested, and the results were therefore based on the nominal concentrations. The results of these studies were considered reliable as the validity criteria for all the tests were satisfied.

The notified polymer will be imported neat into Australia for local reformulation into a variety of personal care products and cosmetic formulations. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations. All wastes including container residues are expected to be disposed of to landfill.

Based on its use in personal care products and cosmetic formulations, it is expected that the majority of the notified polymer will be released to the aquatic compartment through sewers during use. Up to 50% of the notified polymer is expected to adsorb to sludge and sediment during sewage treatment plant (STP) processes, based on its high molecular weight and anionic properties, with sludge eventually disposed of to landfill or re-used for soil remediation. Therefore, the notified polymer is not expected to be released to surface waters at ecotoxicologically significant concentrations. Based on its high molecular weight, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to be bioaccumulative.

All solid wastes including container residues are expected to be disposed of to landfill. Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In both landfill and in surface waters, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulphur.

Therefore, based on its low hazard and assessed use pattern in personal care products and cosmetic formulations, the notified polymer is not considered to pose an unreasonable risk to the environment.