File No PLC/1266

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

2-Propenoic acid, 2-methyl-, dodecyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 2-propenoic acid
(INCI name: VP/Acrylates/Lauryl Methacrylate Copolymer)

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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

July 2015

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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/1266	Ashland Pacific Pty Ltd	2-Propenoic acid, 2-methyl-, dodecyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 2-propenoic acid (INCI name: VP/Acrylates/Lauryl Methacrylate Copolymer)	No	≤2 tonnes per annum	Ingredient in 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 assumed 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

- A person conducting a business or undertaking at a workplace should implement the following controls to minimise occupational exposure to the notified polymer in powder form during handling and reformulation:
  - Local exhaust ventilation system
  - Avoid inhalation of dust
  - Use respiratory protection if ventilation is inadequate

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The SafeWork Australia exposure standard for atmospheric dust is 10 mg/m^3.

- 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;
- the notified polymer is proposed to be used in aerosol spray cosmetics;

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

Applicant
Ashland Pacific Pty Ltd (ABN: 47000075641)
Suite 603, level 6, 2 Burbank Place, Norwest Business Park
Baulkham Hills, NSW 2153

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: Molecular and structural formulae, molecular weight, spectral data, purity, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Chemical Name
2-Propenoic acid, 2-methyl-, dodecyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 2-propenoic acid

CAS Number
83120-95-0

Marketing Name(s)
Acrylidone LM
(INCI name: VP/Acrylates/Lauryl Methacrylate Copolymer)

Other Name
Acrylic acid-dodecyl methacrylate-1-vinyl-2 pyrrolidone copolymer

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
Density	1000 kg/m^3 at 20 °C*
Water Solubility	Expected to have low water solubility based on high molecular weight and predominantly hydrophobic structure.

Dissociation Constant	Not determined. The notified polymer is expected to be ionised in the environment due to the presence of ionic moieties.
Particle Size	>50% of particles are expected to be in respirable range (particle size <10μm)**
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*(M)SDS
**measured by Laser diffraction (Malvern Mastersizer instrument)

5. 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 not be manufactured in Australia. It will be imported as a raw material (at 100% concentration) for use in cosmetic/personal care products. The notified polymer will be reformulated into products at a concentration up to 6%. Public exposure to the notified polymer is expected to be widespread and frequent through daily use of personal care products specifically for hair care, including styling lotions, gels, leave-in conditioning/styling products, shampoos and conditioners. The finished products are also expected to be used professionally in hair salons. The notified polymer will not be used in aerosol spray cosmetics.

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.

Endpoint	***Result***	***Effects Observed?***	***Test Guideline***
Rat, acute oral (notified polymer at 100%)	LD50> 5000 mg/kg bw	Yes[1]	Non-standard protocol
Rabbit, eye irritation (notified polymer at 100%)	Very slightly irritating	Yes[2]	Non-standard protocol
Human, Repeat Insult Patch test (notified polymer at >96%)	Not expected to elicit dermal irritation or sensitization	Yes[3]	Non-standard protocol

1. The notified polymer was found to be not harmful in acute oral toxicity studies. Dyspnea was observed in one animal.
2. The notified polymer was found to be slightly irritating in an eye irritation study; however, it did not meet the criteria for classification as an eye irritant.
3. In a Human, Repeated Insult Patch test (RIPT) among 105 subjects, 6 subjects and 2 subjects exhibited minimal erythema during the induction period and the challenge phase, respectively. These were not considered positive results by the study authors. Therefore, the notified polymer demonstrated no potential dermal irritation or sensitization effects.

All results were indicative of low hazard.

The notified polymer has a high molecular weight (> 10,000 Da), with expected low water solubility. Inhalation of respirable particles of polymers with molecular weights > 70,000 Da has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure (US EPA, 2013). While there is also a concern for polymers with molecular weights between 10,000 and 70,000 Da, it is acknowledged that there is a data gap for this range. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in any effects, as well as the severity of any such effects, is uncertain.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers 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.

Occupational Health and Safety Risk Assessment
Dermal, ocular and inhalation exposure of workers to the notified polymer at <100% concentration in powder form may occur during different stages of reformulation. In this form it may present a risk of lung overloading to workers following inhalation exposure because it is a high molecular weight, water-insoluble polymer with >50% of particulates in the respirable range. The polymer is expected to be slightly irritating to eyes, based on a study in rabbits.

The proposed use of PPE and enclosed, automated processes should minimise the potential for exposure during reformulation. Provided that adequate control measures are in place to minimise worker exposure (including the use of respiratory protection with dust filter and face masks), the risk to formulation workers from use of the notified polymer is not considered to be unreasonable. The Australian recommended exposure standard for dust is 10 mg/m^3 [(NOHSC 3008: (1995)].

Salon workers may experience dermal and ocular exposure to products containing the notified polymer at up to 6%. At this concentration any irritation potential is expected to be greatly reduced. The products containing the notified polymer do not include aerosol sprays; therefore inhalation exposure is not anticipated.

Therefore, given the assumed low hazard and proposed use pattern and the controls associated with the use of the polymer in powder form, the risk to workers posed by the notified polymer is not considered unreasonable.

Public Health and Safety Risk Assessment
The public is expected to be exposed to the products containing the notified polymer at up to 6% during widespread use of personal care products. The principal route of exposure will be dermal, although incidental ocular and inhalation exposure may also occur. The high molecular weight and expected low water solubility of the polymer are expected to limit absorption by all routes. The potential for eye irritation is expected to be greatly reduced at the concentration of use.

Based on the assumed low hazard and the expected pattern of exposure, the risk to the public posed by the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

The notified polymer will not be manufactured in Australia. Release to the environment may only occur in the unlikely event of an accident during transport or an accidental spill. During formulation of hair care products it is estimated that up to 20 kg per annum of the notified polymer will be released into the environment as a result of residues in import containers, spills and equipment cleaning. Subsequent water washes will pass to interceptor pits where the settled material will be collected and disposed of to landfill. Import containers will be rinsed and disposed of to landfill. The rinsate will be collected and disposed of to a liquid waste facility by licensed contractor.

The majority of the notified polymer will be released to sewer as a result of its use in personal care products. Release is assumed to occur daily, and to be diffuse in nature. Under a worst case scenario it will be assumed that 100% of the notified polymer will be washed into sewers. Assuming none of the notified polymer will be removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as 1.21 µg/L [PECriver = 5.48 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC for rivers is well below the EC_{50} for algae of the most toxic anionic polymers (EC_{50} > 1 mg/L). In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it is an anionic polymer and has high molecular weight.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and it is therefore not expected to bioaccumulate. It is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon and nitrogen.

Following use of personal care products containing the notified polymer, empty containers are disposed of through domestic garbage and hence will enter landfill or recycling. The residues in the empty containers are expected to account for approximately 5 % of the import volume.

Based on its assumed low hazard and reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

8. BIBILOGRAPHY

NOHSC (1995) National Commission's Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008(1995)], National Occupational Health and Safety Commission, Canberra, AusInfo

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.

US EPA (2013) High Molecular Weight Polymers in the New Chemicals Program. http://www.epa.gov/oppt/newchems/pubs/hmwtpoly.htm (Accessed 20 June 2015)