File No PLC/977

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN FULL PUBLIC REPORT

Polyacrylate Crosspolymer-6 (Sepimax Zen)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

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

This Full 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

May 2011

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1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Bronson & Jacobs Pty Ltd (ABN 81 000 063 249)
70 Marple Avenue
VILLAWOOD NSW 2163

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, polymer constituents, residual impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Polyacrylate Crosspolymer-6 (Sepimax Zen) (containing the notified polymer at >90% concentration)
Polyacrylate Crosspolymer-6 (INCI Name)

Molecular Weight

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

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

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	Expected to decompose at >200 °C
Density	230 kg/m^3 at 25 °C (untapped)
Water Solubility	The notified polymer is dispersible in water and forms a gel at high concentration. Reported as fully miscible with water at 20ºC (OECD TG 105).
Dissociation Constant	Not determined. The notified polymer is a salt and is expected to be dissociated throughout the environmental pH range (4-9).

Particle Size

METHOD			
Laser diffraction		Sieve analysis	
<371 μm:	90%	<2000 μm:	98%
<4.3 μm:	50%	<150 μm:	25%
<0.8 μm:	10%	<80 μm:	7%

Reactivity: Stable under normal environmental conditions. The notified polymer contains hydrolysable functional groups. However, hydrolysis at ambient temperature is expected to be slow in the environmental pH range (4–9).

Degradation Products: None under normal conditions of use

Comments

The notified polymer was also tested for dust explosibility. Dusts of the notified polymer were determined to have low sensitivity to electric sparks and electrostatic charges (minimum ignition energy (MIE) between 200 and 300 mJ). A typical low MIE would be <25 mJ. The notified polymer had a maximum explosion pressure (P_{max}) = 8.3 bars relative and the maximum rate of pressure increase was determined to be (K_{st}) = 194 bar.m.s^{-1}. Based on these results, the notified polymer is classified as ST1 (moderate explosive potential).

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	<10	<10	<10	<10

Use

The notified polymer will not be manufactured in Australia.

The notified polymer will be imported into Australia at a concentration of >90%.

The notified polymer will be reformulated in Australia into leave-on cosmetic products at a concentration of ≤5%. Its function is as a viscosity increasing agent, thickener-stabiliser or emulsion stabiliser.

6. HUMAN HEALTH RISK ASSESSMENT

Hazard Characterisation

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

	Result	*Effects observed*	*Test Guideline*
Rabbit, skin irritation	Non-irritating at >90%	No	OECD TG 404
Rabbit, eye irritation	Slightly irritating to eye	Yes	OECD TG 405
HET-CAM*, eye irritation	Non-irritating at 2%	No	In-house method
Skin sensitisation, Human Repeat Insult Patch Test	Non-sensitising and non-irritating in human volunteers at ~5%	No	Marzulli-Maibach Method
Genotoxicity - bacterial reverse mutation	Negative	No	OECD TG 471

*HET-CAM = Hens Egg Test - Chorio-Allantoic Membrane

All results were indicative of low hazard.

The notified polymer was found to be slightly irritating to the eye in rabbits. A maximum of grade 2 chemosis and redness of the conjunctiva and slight discharge (grade 1) was reported in all 3 animals. All effects had resolved by Day 6 in 2 animals and by Day 7 in 1 animal. Based on these results, the notified polymer is considered to be slightly irritating to the eye in rabbits.

The notified polymer is a high molecular weight insoluble polymer that has a high percentage (> 50%) of respirable particles (< 10 μm), based on its granulometry obtained by laser diffraction. However, the notified polymer as introduced is unlikely to present an inhalation hazard as it is likely to contain only a very low concentration of respirable particles due to the tendency for the notified polymer to agglomerate into larger particles. Based on the granulometry of the notified polymer obtained by sieve analysis, only 7% of the notified polymer as introduced has a particle size less than 80 μm (SEPPIC 2010).

Occupational Health and Safety Risk Assessment

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. However, as the notified polymer as introduced may contain a small fraction of particulates in the respirable range (<10 μm), there is a potential health risk to workers when handling the notified polymer in the powdered form. Therefore appropriate control measures (e.g. local exhaust ventilation, dusk masks) to mitigate inhalation exposure to respirable particles of the notified polymer should be implemented, and the level of atmospheric dusts should be minimised. The Australian exposure standard for atmospheric dust in the occupational environment is 10 mg/m^3 [NOHSC:3008(1995)].

Occupational exposure is possible for workers in beauty salons using products containing the notified polymer at up to 5%. However, given the assumed low hazard, the risk posed to workers in beauty salons by exposure to the notified polymer is not considered unreasonable.

Based on the assumed low hazard and the assessed use pattern, the risk to occupational health from use of the notified polymer is not considered unreasonable provided control measures are in place to minimise inhalation exposure to dusts of the notified polymer.

Public Health and Safety Risk Assessment

The public may be exposed during use of leave-on cosmetic products containing the notified polymer at ≤5%. However, based on the assumed low hazard, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard. This is supported by environmental endpoints observed in testing conducted on an acceptable analogue polymer.

Endpoint	*Result*	*Effects Observed?*	
Fish Toxicity	LC50 > 100mg/L (WAF)	No	OECD TG 203
Daphnia Toxicity	EC50 > 100 mg/L (WAF)	No	OECD TG 202

All results were indicative of low hazard up to the limit of solubility of the acceptable analogue polymer in water. However, the notified polymer is a water dispersible anionic polymer, to which algae is expected to be the most sensitive species. 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, which applies to the notified polymer. However, the notified polymer toxicity to algae is likely to be reduced due to the pendant position of the acid groups and dilution of the chelating monomer with non-chelating monomers. In addition, the toxicity to algae is likely to be further reduced due to the presence of calcium ions in environmental waters, which will bind to the functional groups.

The majority of the notified polymer will be released to sewage treatment plants, although up to 4% is expected to be disposed of to landfill as residues in import and end-use cosmetic containers. Under a worst case scenario it will be assumed that all of the notified polymer will be washed into sewers. Assuming 90% 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 0.065 µg/L [PEC_{river} = 27.4 notified polymer kg/day ÷ (200 L/person/day × 21.161 million people) × 0.9 (mitigation) × 1 (dilution factor)]. Using the endpoint of LC50 for fish of 100 mg/L (WAF), and an assessment factor of 1000 as endpoints are available for only two trophic levels, the predicted no-effect concentration (PNEC) for the notified polymer in water is predicted to be above 100 µg/L. Therefore, the risk quotient Q (PEC/PNEC) is calculated to be 0.006. Since the Q value is much less than 1, the proposed use of the notified polymer is unlikely to pose an unreasonable risk to aquatic life.

The notified polymer is not expected to cross biological membranes but 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, inorganic salts and oxides of nitrogen and carbon.

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

8. RECOMMENDATIONS

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

- 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 dusts should be maintained as low as possible. The Australian exposure standard for atmospheric dust in the occupational environment is 10 mg/m^3 [NOHSC3008:(1995)].

- Water insoluble high molecular weight polymers used in the respirable size range (< 10 µm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure.

  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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environmental Recommendations

- No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal

- The notified polymer should be disposed to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area.
  - Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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 used in a consumer product in power form.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a component of cosmetics at up to 5% concentration, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased from 10 tonnes, 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 chemical 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 MSDS of the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

BIBLIOGRAPHY

NOHSC (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008 (1995)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Société d'Exploitation de Produits Pur les Industries Chimiques (SEPPIC) (2010) STATEMENT No 10 158 01, 'Justification for classification change of 'SEPIMAX ZEN', p. 1.