File No PLC/1228

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Baycusan C 1004

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

November 2014

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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/1228	Bayer MaterialScience Pty Ltd	Polymer in Baycusan C 1004	No	≤ 30 tonnes per annum	Component of cosmetic products

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

- 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 (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 for the 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 cosmetic products 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 products containing 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
Bayer MaterialScience Pty Ltd (ABN: 18 086 237 765)
17-19 Wangara Road
Cheltenham VIC 3169

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

2. IDENTITY OF POLYMER

Marketing Name(s)
Polymer in Baycusan C 1004 (containing the notified polymer at ≤ 40% in water)
Polyurethane-35 (INCI)

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 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	Milky white aqueous dispersion*
Glass Transition Temp	- 45.5 °C*
Density	1,047 kg/m^3 at 20 °C*
Water Solubility	Not Determined. Based on its high molecular weight and predominantly hydrophobic structure, the notified polymer is expected to have low water solubility.
Dissociation Constant	pKa = 0.5 – 4.5 (based on monomers). The notified polymer contains potential anionic functionalities which are expected to be ionised in the environmental pH range (4 - 9). However, this is not considered to be a concern due to its limited water solubility.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*For Polymer in Baycusan C 1004 (containing the notified polymer at 40% in water)

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-20	1-20	1-30

Use
The notified polymer will be imported as an aqueous dispersion at a concentration of 40% for reformulation, or in finished products containing 5-15% of the notified polymer. The notified polymer will be used in cosmetic products at 5-15%.

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*
1. Rat, acute oral	LD50> 4,890 mg/kg bw	No	OECD TG 423
12. Skin Corrosion	non-corrosive	No	OECD TG 431
4. Rabbit, skin irritation	slightly irritating	Yes	OECD TG 404
5. Rabbit, eye irritation	slightly irritating	Yes	OECD TG 405
6. Skin sensitisation	no evidence of sensitisation.	No	OECD TG 406 (Buehler and Maximisation tests)
8. Genotoxicity - bacterial reverse mutation	non mutagenic	No	OECD TG 471

All results were indicative of low hazard.

In a skin irritation study conducted on three rabbits, there was a slight irritating effect to the skin in all animals. The author noted that the removal of the patch was not possible without altering the response or the integrity of the epidermis in one animal. All irritating effects were reversible within 7 days. The irritant effects were not sufficient to warrant classification of the notified polymer as a skin irritant.

In an eye irritation study conducted on three rabbits, redness conjunctivae was noted in one treated eye in two animals one hour after treatment and in one treated eye in one animal 24 hours after treatment. All irritating effects were reversible within 48 hours. The irritant effects were not sufficient to warrant classification of the notified polymer as an eye irritant.

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

No ecotoxicological data were submitted. The notified polymer is an anionic polymer where anionic polymers are generally of low toxicity to fish and daphnia. However, they 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. However, this does not apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae. In addition, the toxicity to algae is likely to be reduced due to the presence of calcium ions in the aquatic environment, which will bind to the functional groups.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic products that will be washed off the skin. 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 0% 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 18.17 µg/L [PECriver = 82.19 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC is well below the EC_{50} for algae of the most toxic anionic polymers (EC_{50} > 1 mg/L).

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.

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