File No PLC/1159

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

VESTAMID BS1379

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 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

August 2013

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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/1159	Evonik Australia Pty Ltd	VESTAMID BS1379	No	≤ 20 tonnes per annum	Component of plastic articles

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 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

- The notified polymer should be disposed of to landfill.

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 a component of plastic articles, 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
Evonik Australia Pty Ltd (ABN: 31 145 739 608)
Suite 33, 1 Ricketts Road
MT WAVERLY VIC 3149

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 monomers and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
VESTAMID BS1379

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	Solid
Melting Point/Glass Transition Temp	182 °C
Density	1,020 kg/m^3 at 23 °C
Water Solubility	Insoluble. The notified polymer is mainly composed of hydrophobic species and has a high molecular weight (NAMW > 1,000 Da).
Dissociation Constant	Not determined. The notified polymer may contain dissociable functionalities with expected pKa of 4 - 9. However, the notified polymer is not expected to be significantly ionised in the environment due to its limited water solubility.
Particle Size	Introduced as solid granules
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20	< 15	< 15	< 10	< 10

Use
The notified polymer will be imported into Australia at 100% concentration and used in injection and extrusion moulding processes to manufacture plastic articles for industrial applications.

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 an acute oral toxicity study on an analogue in rats that was submitted (conducted according to OECD TG 423; LD50 > 2,000 mg/kg bw).

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

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers with a potential cationic density may have adverse effects on aquatic life. However, given the insolubility of the notified polymer in water, which limits its potential to ionise in the environment, and given the limited release to the environment expected from the proposed use pattern, the notified polymer is not expected to reach an ecotoxicologically significant concentration in the environment.

The notified polymer will be imported into Australia to manufacture plastic articles by injection and extrusion moulding processes. No release of the notified polymer to the aquatic environment is expected from manufacture and reformulation processes.

Most of the notified polymer will be used in the manufacture of plastic articles by injection moulding or extrusion, and be trapped within articles. The plastic articles will finally end up in landfill at the end

of their useful life. Any spills and waste generated from equipment cleaning (up to 2% of the total annul import volume) are expected to be collected and disposed by a waste contractor or treated onsite prior to being disposed of to landfill. Residues of the notified polymer (up to 1%) in the import containers are expected to be disposed of to landfill with the empty containers. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic pathways to form water and oxides of carbon and nitrogen.

The notified polymer is not expected to be readily biodegradable. However, due to its high molecular weight it is not expected to cross biological membranes and is therefore not expected to bioaccumulate.

Therefore, based on its assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.