NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

VESTAMID HTplus TGP3577

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 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

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Table of Contents

SUMMARY	2
CONCLUSIONS AND REGULATORY OBLIGATIONS	2
ASSESSMENT DETAILS	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF POLYMER	4
3. PLC CRITERIA JUSTIFICATION	4
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	5
6. HUMAN HEALTH RISK ASSESSMENT	5
7. ENVIRONMENTAL RISK ASSESSMENT	5
BIBLIOGRAPHY	5

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/1158	Evonik Australia Pty Ltd	VESTAMID HTplus TGP3577	No	≤ 15 tonnes per annum	Component of plastic articles for industrial applications

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 engineering controls and safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Low dust handling techniques should be implemented.
 - Exhaust ventilation should be used if fumes are generated during moulding and/or dusts are generated.
- 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.

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

Environmental Recommendations

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

• 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 for industrial applications, 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)

Suites 33 & 37 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, reactive functional groups, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

VESTAMID HTplus TGP3577

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 Granules, colour variable on product grade

Melting Point/Glass Transition Temp 235-240 °C

Density 1080 kg/m³ at 23 °C

Water Solubility Not determined. Expected to be low based on its

predominantly hydrophobic structure and high molecular

weight.

Dissociation Constant Not determined. The notified polymer may contain

dissociable functionalities with expected pKa ~4 and ~9. However, the notified polymer is not expected to be significantly ionised in the environment due to its limited

water solubility.

Particle Size Granular

Reactivity The notified polymer contains functionalities that may

hydrolyse. However, significant hydrolysis of the notified

polymer is not expected given its insolubility in water.

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	<10	<10	5-15	5-15	<10

Use

The notified polymer will be imported into Australia as granules in neat form and used in injection and extrusion moulding 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 of an analogue of the notified polymer in rats that was submitted (conducted according to OECD TG 423; LD50 > 2,000 mg/kg bw).

The notified polymer will be imported and used as granules. The (M)SDS indicates that mechanical loading (abrasion) may cause the production of dusts of the notified polymer; however, low dust handling techniques are expected to be implemented. Gasses, vapours or dusts that are harmful to health are not expected to be released provided that the prescribed processing temperature of about 330 °C is not exceeded.

The notified polymer is for industrial applications and the public is not expected to be exposed to articles containing the notified polymer. 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. 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 low release to the environment expected from the proposed use pattern, the notified polymer is not expected to be a concern in the environment.

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. Release of the notified polymer to the aquatic environment is not expected during article manufacturing as residues in equipment washings are expected to be collected and disposed of to landfill. Any residue in the import containers is also 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.

Due to its high molecular weight, the notified polymer is not expected to cross biological membranes and it 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.

BIBLIOGRAPHY

Bioservice (2008) Acute Oral Toxicity (Acute Toxic Class Method) with PA613. (Project No. 083322, November, 2008). Planegg, Germany, BSL Bioservice Scientific Laboratories GmBH. (Unpublished report submitted by the notifier).