

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

Dodecanedioic acid, polymer with 11-aminoundecanoic acid, nonanedioic acid and piperazine

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and the Department of the Environment and Energy, has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

This Public Report is 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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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
SAPLC/198	Bostik Australia Pty Ltd	Dodecanedioic acid, polymer with 11-aminoundecanoic acid, nonanedioic acid and piperazine	No	≤ 5 tonnes per annum	Adhesive for textiles

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 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;
 - the notified polymer is intended to be imported in powder form with respirable particles size ($< 10 \mu\text{m}$).

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from an adhesive for textiles, 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.

Safety Data Sheet

The SDS of the notified polymer containing the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

BOSTIK AUSTRALIA PTY LTD (ABN 79 003 893 838)
51 – 71 High Street
Thomastown VIC 3074

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: molecular formula, structural formula, molecular weight, polymer constituents and import volume.

2. IDENTITY OF POLYMER

Marketing Name

PLATAMID® M1276

Chemical Name

Dodecanedioic acid, polymer with 11-aminoundecanoic acid, nonanedioic acid and piperazine

CAS Number

118106-10-8

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	110-115 °C
Density	1.100 kg/m ³ at 20 °C
Water Solubility	not soluble at 20 °C
Particle Size	0% < 10 µm 8% < 100 µm
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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	5	5	5	5	5

5.1 Mode of Introduction

The notified polymer will be imported in powder form, packaged in 25 kg waterproof poly-lined bags.

5.2 Reformulation/manufacture processes

The notified polymer will not be reformulated nor manufactured in Australia.

The notified polymer will be imported in neat form (100%) as PLATAMID® M 1276 PA 300/80. This product can be extruded or alternatively can be dissolved in solvents. Therefore, it can be either used directly by heat melting or dissolved in solvents at room temperature (or higher depending on the solvent) for use as a solution.

5.3 Use

The notified polymer will be mainly used as an interlining adhesive between pieces of fabrics in the textile/garment business. The notified polymer will be placed between two pieces of fabric and the sandwich assembly will then be pressed using heat to fix.

6. HUMAN HEALTH RISK ASSESSMENT

6.1 Occupational Exposure

Transport and warehouse workers would only be exposed to the notified polymer in the unlikely event of accidental breakage of the waterproof bags or rigid containers.

The notified polymer, which is imported in powder-form, will be poured from bags into various smaller containers, with little or no contact with the operators' skin. Usual protection against dust will be applied (See SDS).

Processing of the polymer requires the heating of the powders between layer of fabrics or other material at a temperature above the melt temperature of the notified polymer. The processing temperature should be above 150 °C and workers will wear heat resistant gloves, eye protection and heat resistant industrial clothing to protect against the hot machines. The normal processing temperature is well below the decomposition temperature. These measures will also prevent exposure to the notified polymer. Good ventilation and proper dust collecting equipment should be available.

6.2 Public Exposure

The notified polymer is intended only for use in industry and as such direct public exposure to the notified polymer is not expected.

No toxicological data were available. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

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

Although not considered in this risk assessment, the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System for the 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.

The notified polymer is a high molecular weight water insoluble polymer ($M_n > 10,000$ Da). 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, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new>, accessed on 26 May 2017). 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. Therefore, there is uncertainty for the potential for lung overloading effects with respect to the notified polymer, if it is used in a form with potential to release respirable particles. 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 the effect(s), are uncertain.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

7.1.1 ENVIRONMENTAL RELEASE

The majority of the release of the notified chemical to the environment from use will be from accidental spills and leaks, and from disposal of empty packaging. Accidental spills and leaks during use will be physically contained and collected, and disposed of to landfill in accordance with local government regulations. Residues may be swept, whilst avoiding creating dust, and should be disposed of by authorized landfill. The notified polymer will be heat transferred onto textiles. Once transferred, the notified chemical is expected to be stable and strongly fixed to the textile substrate and be immobile. The notified polymer is expected to share the fate of the textiles, which are expected to be disposed of to landfill. Empty packaging containing residues of the notified polymer are expected to be disposed of to landfill. Hence, the majority of the total import volume of the notified polymer is expected to be disposed of to landfill.

7.1.2 ENVIRONMENTAL FATE

The polymer in landfill is expected to undergo in-situ degradation by biotic and abiotic process to form landfill gases, including methane, oxides of carbon and water vapour.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

7.3. Environmental Risk Assessment

It is expected that most of the notified polymer will be disposed of to landfill at the end of its useful life. No significant aquatic release is expected.

Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In landfill, the notified polymer is bound within a polymer matrix, and is not expected to be bioavailable or mobile. Due to its high molecular weight and expected low water solubility, the notified polymer is not expected to cross biological membranes and is, therefore, not expected to bioaccumulate. In landfill, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form methane, water and oxides of carbon.

Therefore, based on its assumed low hazard, limited expected aquatic exposure and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the

environment.