

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

### POLYMER OF LOW CONCERN PUBLIC REPORT

**Z-155**

**(INCI Name: Polyurethane-62)**

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.

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**

October 2015

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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/1260	Lubrizol	Z-155 (INCI Name: Polyurethane-62)	No	≤ 100 tonnes per annum	Component of cosmetics

## 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 of 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 a component of cosmetics, 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 a product 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

Lubrizol International, Inc. (ABN 52 073 495 603)  
28 River Street  
SILVERWATER NSW 2128

#### 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/impurities, use details and import volume.

### 2. IDENTITY OF POLYMER

#### Marketing Name(s)

Z-155

#### Other Name(s)

Polyurethane-62 (INCI Name)

#### Molecular Weight

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

### 3. PLC CRITERIA JUSTIFICATION

#### Criterion

Molecular Weight Requirements  
Functional Group Equivalent Weight (FGEW) Requirements  
Low Charge Density  
Approved Elements Only  
Stable Under Normal Conditions of Use  
Not Water Absorbing  
Not a Hazard Substance or Dangerous Good

#### Criterion met

Yes  
Yes  
Yes  
Yes  
Yes  
Yes  
Yes

The notified polymer meets the PLC criteria.

### 4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	White to off-white powder
Melting Point/Glass Transition Temp	Not determined
Density	1,500 kg/m <sup>3</sup> at 23 °C
Water Solubility	Dispersible
Dissociation Constant	Not determined. The notified chemical does not contain any functional groups that are expected to dissociate in water.
Particle Size	50-1000 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	20-25	30-35	40-50	60-75	75-100

#### Use

The notified polymer will not be manufactured in Australia. The notified polymer will be imported as a component of finished cosmetic products, or it may be imported neat as a powder for formulation of cosmetic products within Australia. The finished cosmetic products will contain the notified polymer at < 2% concentration.

## 6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard.

The notified polymer is a high molecular weight (> 70,000 Da) polymer with low water solubility. Inhalation 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. If the notified polymer is inhaled at low levels and/or infrequently, it is assumed that it will be cleared from the lungs.

#### Occupational Health and Safety Risk Assessment

The notified polymer will be introduced neat as a powder for formulation of cosmetic products. The notified polymer is not expected to contain respirable particles (< 10 µm) at significant levels; therefore lung overloading effects are not expected. Furthermore, transfer, blending and packaging processes are expected to be highly automated and fully enclosed.

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

#### Public Health and Safety Risk Assessment

The finished products containing the notified polymer for consumer use will not be applied as an aerosol spray; hence inhalation exposure is not expected.

Therefore, under the proposed use scenario, the risk of the notified polymer to public health is not considered to be unreasonable.

## 7. ENVIRONMENTAL RISK ASSESSMENT

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

The notified polymer will not be manufactured in Australia. Release to the environment may only occur in the unlikely event of an accident during transport or an accidental spill. Release of the notified polymer to the aquatic environment is not expected during reformulation as any accidental spills are expected to be collected by inert material and disposed of according to local regulations. Some of the notified polymer may remain as residue in empty import containers (approximately 1% of the total annual import volume) or empty end-use containers, which is expected to be disposed of to landfill along with the empty containers.

The majority of the notified polymer will be released to sewer as a result of its use in cosmetic products. 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 none 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 60.58 µg/L [ $\text{PEC}_{\text{river}} = 273.97 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 22.613 \text{ million people}) \times 1 \text{ (dilution factor)}$ ]. The PEC for rivers is below the  $\text{EC}_{50}$  for algae of the most toxic anionic polymers ( $\text{EC}_{50} > 1 \text{ mg/L}$ ). In sewage treatment plants, most of the notified polymer is expected to partition to sludge and sediments as it has high molecular weight.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and it is therefore not expected to bioaccumulate. The notified polymer is not readily biodegradable (0% in 28 days) and is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon and nitrogen.

Following use of cosmetic products containing the notified polymer, empty containers are disposed of through domestic garbage and hence will enter landfill or recycling. The residues in the empty containers are expected to account for approximately 5 % of the import volume.

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