File No PLC/1440

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Z-183

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 and Energy.

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

October 2017

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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/1440	Lubrizol International Inc	Z-183	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

- Water insoluble high molecular weight polymers in the respirable size range (< 10 μm) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure if dust or aerosol formation is expected when handling the notified polymer.

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

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer when dust formation is expected during handling:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3.

- 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 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;
- the polymer is intended to be used in aerosol cosmetic spray products;

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.

Safety Data Sheet
The SDS of 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
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, CAS number, molecular and structural formulae, molecular weight, spectra data, purity, polymer constituents, residual monomers/impurities, import volume, and use details.

2. IDENTITY OF POLYMER

Marketing Name(s)
Z-183

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	Off-white solid pellets
Melting Point/Glass Transition Temp	Not determined, expected to be high based on high molecular weight
Density	Not determined, estimated to be 1,000 kg/m^3 at 20 °C (SDS)
Water Solubility	Expected to be low based on the predominantly hydrophobic structure of the notified polymer
Dissociation Constant	Not expected to ionise significantly in the environmental pH range (4-9)
Particle Size	Not determined (imported as pellets or in solutions)
Reactivity	Not expected to be reactive based on structure
Degradation Products	Not expected under normal use conditions

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	25	35	50	75	100

Use
The notified polymer will be used as a component of cosmetics. No manufacturing of the notified polymer will be carried out in Australia. It will be imported in neat form (100%) and formulated by Australian cosmetics manufacturers, or imported in end-use cosmetic products containing the notified polymer at 0.25–1% concentration. The notified polymer will not be used in aerosol spray products.

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 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.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of 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 water-insoluble high molecular weight (Mn > 10,000 Da) polymer with certain fractions of the molecules > 70,000 Da. 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 (US EPA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/high-molecular-weight-polymers-new, accessed on 31 May 2017). However, the notified polymer is not expected to be used in spray products that may generate aerosols during normal use.

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 56.18 μg/L. The PEC for rivers is below the EC50 for algae of the most toxic anionic polymers (EC50 > 1 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 expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon and nitrogen.

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