File No PLC/1017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Hexanedioic acid, polymer with 1,2,3-propanetriol and 2,2,4-trimethyl-1,3-pentanediol (INCI name: Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This notification has been carried out under the signed cooperative arrangement with Canada. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing. In conjunction with the Department of Sustainability, Environment, Water, Population and Communities, NICNAS conducts the risk assessment for environmental, public health and occupational health and safety.

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

July 2012

Table of Contents

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/1017	Bronson & Jacobs Pty Ltd	Hexanedioic acid, polymer with 1,2,3-propanetriol and 2,2,4-trimethyl-1,3-pentanediol (INCI name: Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer)	No	≤ 1 tonne per annum	A component of personal care and cosmetic products

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 MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed 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 personal care and cosmetic products, or is likely to change significantly;
- the amount of notified polymer being introduced has increased per annum, 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 MSDS of the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant
Bronson & Jacobs Pty Ltd (ABN 81 000 063 249)
70 Marple Avenue
VILLAWOOD NSW 2163

Exempt Information (Section 75 of the Act)
No details are claimed exempt from publication.

NOTIFICATION IN OTHER COUNTRIES
Canada (2002)

2. IDENTITY OF POLYMER

Marketing Name
Lexorez 200

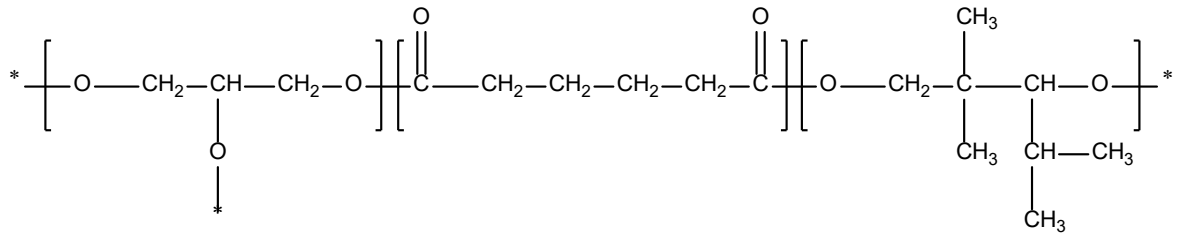
Chemical Name
Hexanedioic acid, polymer with 1,2,3-propanetriol and 2,2,4-trimethyl-1,3-pentanediol

CAS Number
282527-44-0

Other Name(s)
Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer (INCI name)

Molecular Formula
$(C_8H_{18}O_2.C_6H_{10}O_4.C_3H_8O_3)x$

Structural Formula



Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da.

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Low MW Polyester Manufactured from Allowable Reactants	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light amber viscous liquid
Melting Point/Glass Transition Temp	< 25°C
Density	1,130 kg/m^3 at 25 °C
Water Solubility	A low water solubility is expected based on structure of the notified polymer.
Reactivity	Stable under normal environmental conditions. The notified polymer contains hydrolysable functional groups. However, hydrolysis is not expected to be significant in the environmental pH range of 4-9 due to the chemical nature of the functional groups and the low water solubility of the notified polymer.
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	1	1	1	1	1

Use
The notified polymer will not be manufactured within Australia but will be imported, at a concentration of up to 10%, as a component of cosmetic ingredients. The notified polymer may be reformulated at concentrations up to 10% for use in a wide range of personal care and cosmetic products including products where it will be applied as a spray.

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 tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 > 2000 mg/kg bw	yes	OECD TG 401
Rabbit, skin irritation	non-irritating	no	OECD TG 404
Rabbit, eye irritation	slightly-irritating	yes	OECD TG 405
Genotoxicity - bacterial reverse mutation	non mutagenic	no	Similar to OECD TG 471

All results were indicative of low hazard.

The effects seen in the acute oral toxicity study included weight loss in 2/10 individuals and abnormalities (lung and kidney) and alopecia in 6/10 animals at necropsy. All animals survived to the end of the test period.

The effects seen in the eye irritation study were limited to slight conjunctival irritation in all three test subjects which cleared by the 72 hour observation.

The notified polymer is not expected to be irritating to the respiratory system based on the lack of irritancy seen in the skin and eye studies. The notified polymer does have a high proportion of low molecular weight species and one of the monomers, hexanedioic acid, is a severe eye irritant. However, the notifier states that there should be no residual monomer present in the polymer and the majority of the irritation potential from the carboxylic acid functional groups will be lost during the reaction of the hexanedioic acid with the alcohol based monomers to form the polyester. The notified polymer is also not expected to be toxic by inhalation due to the low toxicity of all the monomers by a number of routes (including inhalation) and the low acute oral toxicity of the notified polymer itself.

Occupational Health and Safety Risk Assessment
The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is further supported by the limited toxicological data provided on the notified polymer. However, based on the toxicological studies provided by the notifier, the notified polymer may present as a slight eye irritant.

The notified polymer will be introduced into Australia at a concentration of ≤ 10% and at such concentrations is not expected to be irritating. Overall based on the low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

Public Health and Safety Risk Assessment
There will be widespread and repeated exposure of the general public to the notified polymer through the use of personal care and cosmetic products. The principal route of exposure will be dermal and ocular. The notified polymer is considered to be a slight eye irritant. However, given the low concentration (≤ 10%) of the notified polymer in personal care and cosmetic products, the risk of irritation is expected to be low. Products containing the notified polymer may be applied as a spray, however the notified polymer is not expected to be hazardous via inhalation. Overall, based on the

assumed low hazard and the low concentration in personal care and cosmetic products, the notified polymer is not considered to pose an unreasonable risk to public health.

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 is expected to be washed to a sewer as a result of its use in personal care and cosmetic products. The environmental releases of the notified substance would occur through consumer usage of products containing the notified substance. This would result in nearly 100% discharge of the notified substance to the sewer system.

No biodegradation information was supplied with this notification. The notified substance contains ester groups which have the potential to hydrolyse. However, the hydrolysis would be a slow process in the environmental pH range of 4 – 9. The notified polymer has a number average molecular weight greater than 1,000 daltons, with a relatively high proportion of components at a molecular weight < 1,000 daltons. The larger components are not expected to cross biological membranes, leaving little potential for bioaccumulation. The ability of the low molecular weight components to cross biological membranes, due to molecular size however, cannot be eliminated as a proportion of the components are smaller than 1,000 daltons. However, polyester polymers are generally not considered to be a concern to aquatic organisms.

Under a worst case scenario it will be assumed that 100 % of the notified polymer will be washed into sewers. Assuming 0 % 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 0.61 µg/L [PECriver = 2.74 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)].

If released to aquatic environments, the notified polymer would be expected to partition to sediment and undergo slow biodegradation, forming water and oxides of carbon. Therefore, the notified polymer is expected to remain well below concentrations that could be harmful to aquatic life as polymers of this nature are considered to be of low concern to the aquatic environment.

Therefore, the notified polymer is not considered to pose an unreasonable risk to the environment.