

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

POLYMER OF LOW CONCERN PUBLIC REPORT

1,4-Butanediol, polymer with 5-amino-1,3,3-trimethylcyclohexanemethanamine, α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane

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**

February 2019

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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/208	Flint Group Australia Pty Ltd	1,4-Butanediol, polymer with 5-amino-1,3,3-trimethylcyclohexanemethanamine, α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane	No	≤ 70 tonnes per annum	Component of inks

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 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.

Environment

- The following control measures should be implemented to minimise environmental exposure during mixing and use of the notified polymer:
 - Spills should be collected with absorbing material and sent away as waste.

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.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:
 - Store in areas without drains.

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 inks, 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 product 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

Flint Group Australia Pty Ltd (ABN: 006 659 178)
25-51 Berends Drive
DANDENONG SOUTH VIC 3175

Notification Category

Self Assessment: Polymer of Low Concern

Exempt Information (Section 75 of the Act)

No details are claimed exempt from publication

Previous Notification in Australia By Applicant(s)

None

Notification in Other Countries

EC, The polymer meets the polymer definition in REACH and it is registration exempted.
US, TSCA Polymer Exemption

2. IDENTITY OF POLYMER

Marketing Name(s)

Printpur HM 434 (product containing the notified polymer at 54-56% concentration in ethanol/ethyl acetate)

Chemical Name

1,4-Butanediol, polymer with 5-amino-1,3,3-trimethylcyclohexanemethanamine, α -hydro- ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)] and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane

CAS Number

Not allocated

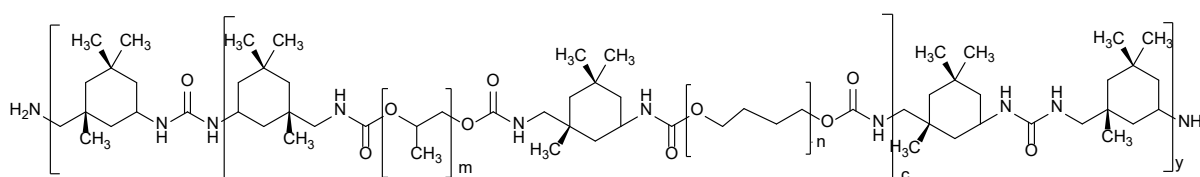
Other Name(s)

Polypropylene glycol, polymer with isophorone diisocyanate, 1,4-butanediol and isophoronediamine

Molecular Formula

$(C_{12}H_{18}N_2O_2 \cdot C_{10}H_{22}N_2 \cdot C_4H_{10}O_2 \cdot (C_3H_6O)_n H_2O)_x$

Structural Formula



Molecular Weight

Number Average Molecular Weight (Mn)	13,536 g/mol
Weight Average Molecular Weight (Mw)	33,679 g/mol
Polydispersity Index (Mw/Mn)	2.49
% of Low MW Species < 1000 g/mol	0
% of Low MW Species < 500 g/mol	0

Reactive Functional Groups

Functional Group	Category	Equivalent Weight (FGEW)
Amine	High Concern/Potentially Cationic	> 5,000 g/mol based on end group analyses

The NCO groups are totally reacted and the total absence of these reactive groups can be demonstrated with a titration (addition of isobutyl amine and titration with HCl) or with FT-IR analysis (absence of the typical NCO signal at 2275 cm⁻¹).

Polymer Constituents

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Poly[oxy(methyl-1,2-ethanediyl)], α -hydro- ω -hydroxy-1,4-Butanediol	25322-69-4 110-63-4	75.73 0.67	0 0
Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl	4098-71-9	17.18	0
Cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-	2855-13-2	6.42	0

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Limpid solution (54-56% solution in ethanol/ethyl acetate)
Melting Point/Glass Transition Temp	< - 54 °C
Density	915 kg/m ³ at 25 °C
Water Solubility	Expected to be low based on the predominantly hydrophobic structure of the notified polymer.
Dissociation Constant	The notified polymer contains terminal functional groups which are expected to ionise under environmental conditions (pH 4-9).
Particle Size	Not applicable as the notified polymer is prepared and used in solution
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

Comments

The notified polymer is likely to be stable under normal conditions of use. Although it contains carbamate linkages, hydrolysis of the polymer is unlikely to occur in the pH range of 4-9.

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	60	70	70	70	70

Mode of Introduction

The notified polymer will be imported in drums or IBC containers as 55% solution in ethyl acetate and ethanol.

Reformulation/manufacture processes

The notified polymer will be reformulated at the notifier's site by addition of small amounts of other components to produce coloured inks dispersions, containing approximately 40% notified polymer and packaged generally in 200 L steel drums or smaller steel pails. These will be distributed to industrial printing sites where the inks will be applied.

Use

The notified polymer is a not reactive, film forming binder used in the formulation of flexo and gravure printing inks for application in laminated packaging.

6. HUMAN HEALTH RISK ASSESSMENT

Occupational Health and Safety Risk Assessment

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

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

Dermal and ocular exposure may occur during ink preparation and printing processes. However, exposure to significant amounts of the notified polymer is limited given the use of engineering controls and personal protective equipment by workers.

Public Health and Safety Risk Assessment

The notified polymer will not be available to the public. Members of the public may come into contact with products containing the notified polymer. Once the ink dries, the polymer would be trapped in a laminate or surface printed plus an over lacquer systems, and therefore dermal exposure to the notified polymer from contact with the dried ink is not expected.

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

7.1. Exposure Assessment

Environmental Release

The notified polymer will be imported in formulated inks. A small amount (< 1%) of the notified polymer could be washed off from printing machinery during the normal cleaning process using an organic solvent mix. A licensed disposal contractor for off-site solvent regeneration will deal with any waste generated, with the notified polymer being disposed of to landfill.

Residues remaining in the import containers (1-2%) will be disposed of either through metal recycling companies or the controlled waste system (plastic cans) or washed and sent to landfill.

The majority of the notified polymer will be bound within the cured coating matrix adhering to printing inks, varnishes and self-adhesive labels. Once the polymer is within a cured coating it is likely to share the fate of the substrate, which might involve recycling or landfill.

Environmental Fate

The notified polymer contains hydrolysable functionalities, but is expected to be stable under normal environmental conditions (pH 4-9). Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse or settle to sediment. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Thermal decomposition of the notified polymer during metal recycling of substrates will result in the formation of water vapour and oxides of carbon and nitrogen.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. The notified polymer contains terminal functionality which has the potential to become cationic under environmental conditions (pH 4–9). However, the cationic charge density is > 5,000 g/mol. Therefore, the notified polymer is not expected to be toxic to aquatic organisms based on the reported use pattern.

7.3. Environmental Risk Assessment

The notified polymer will be used as binder for the production of single web prints as well as laminated systems. Once these inks have been dried the notified polymer is expected to remain within the product matrices. Hence, the majority of the notified polymer will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or thermally decomposed during the metal reclamation process. In landfill it is expected that the notified polymer will remain immobile within the soil. Thermal decomposition of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.