

File No SAPLC/116

November 2010

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

**FULL PUBLIC REPORT**

**Cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, polymer with ethanol,  $\alpha$ -hydro- $\omega$ -hydroxy-poly[oxy(methyl-1,2-ethanediyl)], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-cyclohexane and 1,1'-methylenebis[4-isocyanatobenzene]**

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* (Cwlth) (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 Ageing and the Department of Sustainability, Environment, Water, Population and Communities has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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**

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**1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT

Flint Group Australia Pty Ltd (ABN 79 006 659 178)  
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 follow in the polymer definition in REACH and it is registration exempted.  
US, TSCA Polymer Exemption

**2. IDENTITY OF CHEMICAL**

## CHEMICAL NAME

Cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, polymer with ethanol,  $\alpha$ -hydro- $\omega$ -hydroxy-poly[oxy(methyl-1,2-ethanediyl)], 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethyl-cyclohexane and 1,1'-methylenebis[4-isocyanatobenzene]

## OTHER NAME(S)

Polypropylene glycol, polymer with MDI, isophorone diisocyanate, isophoronediamine and ethanol

## MARKETING NAME(S)

Printpur HM 426 (product containing the notified polymer at 44%)

## CAS NUMBER

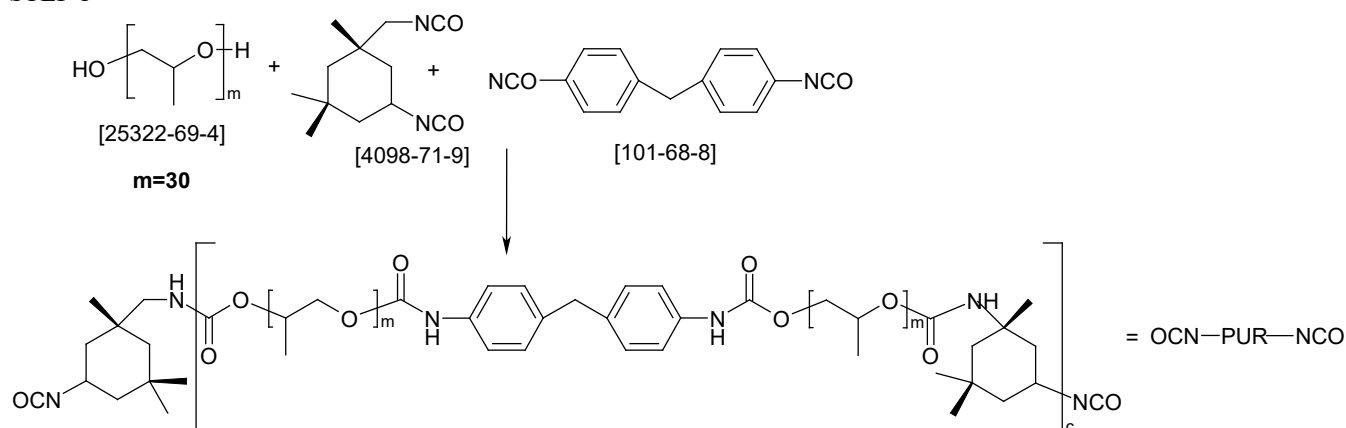
None Allocated

## MOLECULAR FORMULA

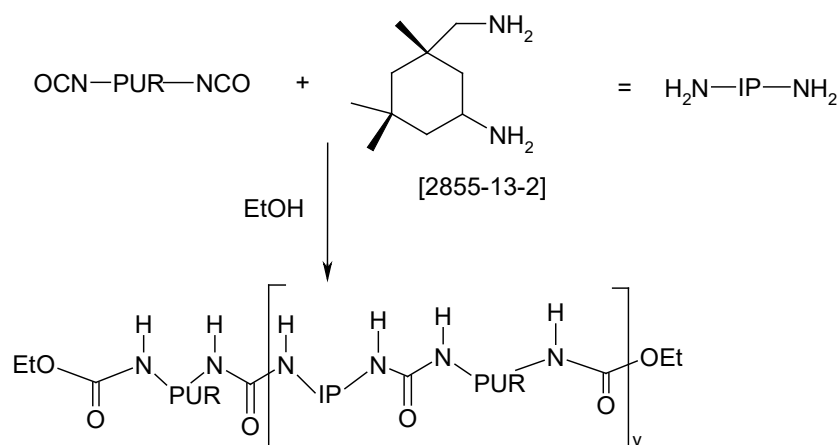
$C_2H_6O \cdot ((C_3H_6O)_n \cdot H_2O) \cdot C_{10}H_{22}N_2 \cdot C_{12}H_{18}N_2O_2 \cdot C_{15}H_{10}N_2O_2$

## STRUCTURAL FORMULA

## STEP 1



## STEP 2 and final structure formula



## MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) 25,176 Da

Weight Average Molecular Weight (WAMW) 71,773 Da

Polydispersity Index (WAMW/NAMW) 2.85

% of Low MW Species &lt; 1000 0

% of Low MW Species &lt; 500 0

## POLYMER CONSTITUENTS

Chemical Name	CAS No.	Weight % starting	Weight % residual
Poly[oxy(methyl-1,2-ethanediyl)], $\alpha$ -hydro- $\omega$ -hydroxy-	25322-69-4	80.7	0
Benzene, 1,1'-methylenebis[4-isocyanato-	101-68-8	9.3	0
Cyclohexane, 5-isocyanato-1-(isocyanatomethyl)-	4098-71-9	5.5	0
1,3,3-trimethyl-			
Cyclohexanemethanamine, 5-amino-1,3,3-	2855-13-2	4.0	0
trimethyl-			
Ethanol	64-17-5	0.5	0

## REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

### 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

<b>Appearance at 20°C and 101.3 kPa</b>	Imported in yellowish transparent solution (44% solution in ethanol/ethyl acetate)
<b>Glass Transition Temp</b>	< - 30°C
<b>Density</b>	950 kg/m <sup>3</sup> at 25°C
<b>Water Solubility</b>	The notified polymer is expected to have low water solubility due to the predominantly hydrophobic character of its monomers. This is confirmed by the following test: 1 g of polymer solution was precipitated under stirring in 1 L water at 20°C. After filtration no trace of polymer was found in the liquid phase.
<b>Dissociation Constant</b>	No acid or base groups are present
<b>Particle Size</b>	Not applicable as the notified polymer is prepared and used in solution.
<b>Reactivity</b>	Stable under normal environmental conditions
<b>Degradation Products</b>	None under normal conditions of use
<b>Comments</b>	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 environmental 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>
<i>Tonnes</i>	60	70	70	70	70

USE AND MODE OF INTRODUCTION

#### **Mode of Introduction**

Printpur HM 426, containing 44% notified polymer as a solution in ethanol/ethyl acetate, will be imported via Sydney or Melbourne in 200 L steel barrels. It will be transported by road to an ink production site of Flint Group in Australia.

#### **Reformulation/manufacture processes**

The notified polymer will be reformulated at the Flint Group sites in Australia by addition of other

components to produce whites and coloured ink dispersions, containing approximately 20% notified polymer, and packaged generally in 200 L steel drums, but sometimes in 20 L steel pails. These will be distributed to the customer printing converter facilities where the inks will be applied, dried and printed in various packaging plants.

#### **Use**

The polymer will be used as a binder in printing inks for flexible packaging systems and it will be used at approximately 20% in the final liquid Ink. The ink layer will be applied as surface print or reverse printed and laminated using films such as oriented polypropylene (OPP), low density polyethylene (LDPE), polyethylene terephthalate (PET), polyamide (PA) or Aluminum Foil (laminated systems).

The use of the notified polymer is 100% for industrial applications and it will not be available to the general public.

## **6. HUMAN HEALTH IMPLICATIONS**

### **6.1. Exposure Assessment**

#### **OCCUPATIONAL EXPOSURE**

The ink containing the notified polymer is intended only for use in industry.

Dermal and ocular exposure may occur during reformulation and certain 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 EXPOSURE**

The ink containing the notified polymer will not be available to the public. The public may have contact with the dried ink on packaging. However 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.

### **6.2. Toxicological Hazard Characterisation**

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

### **6.3. Human Health Risk Assessment**

#### **OCCUPATIONAL HEALTH AND SAFETY**

Although exposure to the notified polymer could occur during the ink preparation and during the printing process, the risk to workers is considered to be low due to the workplace controls in place and the assumed intrinsic low hazard of the notified polymer.

#### **PUBLIC HEALTH**

As there will be very low exposure of the public to the notified polymer and the polymer is assumed to be low hazard, the risk to the public from exposure to the notified polymer is considered to be negligible.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Exposure Assessment**

#### **ENVIRONMENTAL RELEASE**

The notified polymer will be imported to formulate ink. 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 this, 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) and be disposed of by incineration 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. Approximately 50% of the paper products on which the ink will be printed are expected to be recycled. As a result of the de-inking process during recycling, the notified polymer will be released to STPs.

#### **ENVIRONMENTAL FATE**

The notified polymer contains groups in the backbone that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. 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 at STPs it is expected to adsorb to the sludge, 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. Incineration of the notified polymer during metal reclamation will result in the formation of water vapour and oxides of carbon and nitrogen.

### **7.2. Environmental Hazard Characterisation**

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

### **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 ink 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, recycled or incinerated at the end of their useful lifetime. In landfill it is expected that the notified polymer will remain immobile within the soil. In STPs the notified polymer is expected to adsorb to sludge. In soil and sludge the notified polymer is expected to slowly degrade by biotic and abiotic processes to water and oxides of carbon and nitrogen. Incineration of the notified polymer during metal reclamation will result in the formation of water vapour and oxides of carbon and nitrogen. Due to the notified polymer's high molecular weight, it is not expected to bioaccumulate.

## **8. CONCLUSIONS**

### **8.1. Level of Concern for Occupational Health and Safety**

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

### **8.2. Level of Concern for Public Health**

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

### **8.3. Level of Concern for the Environment**

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

## 9. RECOMMENDATIONS

### CONTROL MEASURES

#### Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer and other ingredients in the product Printpur HM 426:
  - Adequate exhaust ventilation should be used to control solvent vapors
  - Employers should ensure that the NOHSC exposure standards for solvent vapors are not exceeded in the workplace
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer and other ingredients in the product Printpur HM 426:
  - Eye protection, impermeable gloves, overalls and industrial footwear
- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must 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

- The notified polymer should be disposed of to landfill.

#### Storage

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

#### Emergency procedures

- Spills/or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

## 10. REGULATORY OBLIGATIONS

### 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 chemical has changed from a binder in printing inks, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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 notifier has provided an MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the notifier.