

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

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Printpur HM 431

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 the Department of the Environment, 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 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:

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**Director
NICNAS**

February 2016

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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/182 | Flint Group Australia Pty Ltd | Polymer in Printpur HM 431 | 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 (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 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 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.

(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

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)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, and polymer constituents.

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

Marketing Name(s)

Printpur HM 431 (product containing the notified polymer)

Molecular Weight

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

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 |

4. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|----------------------------------|--|
| Appearance at 20°C and 101.3 kPa | Yellowish Transparent Solution (54–56 % solution in Ethanol / Ethyl Acetate) |
| Glass Transition Temp | < -40 °C |
| Density | 920 kg/m ³ at 25 °C |
| Water Solubility | Expected to be low based on the predominantly hydrophobic structure of the notified polymer. |
| Dissociation Constant | Not determined. The notified polymer contains terminal functional groups that are expected to be ionised in the environmental pH range (pH 4–9). |
| 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> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | 60 | 70 | 70 | 70 | 70 |

Mode of Introduction

Printpur HM 431 is a solution containing 55% notified polymer in ethanol and ethyl acetate. It is imported via Sydney or Melbourne in 180 L steel barrels. It is 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 white and colored 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 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 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).

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

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 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 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 chemical would be trapped in a laminate or surface printed plus an over lacquer systems, and therefore dermal exposure to the notified chemical 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. 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.

6.3 Human Health 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 intrinsic low hazard of the notified polymer.

PUBLIC HEALTH

As there will be no exposure of the public to the notified polymer, the risk of the notified polymer to the public is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will be imported as a component of printing inks for flexible packaging systems. Reformulation of the notified polymer will take place in Australia. Accidental spills/leaks of the notified polymer during blending are expected to be contained in a bunded area, collected and disposed of to landfill.

A small amount (<1%) of the notified polymer is expected to 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 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 chemical 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 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 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. In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, eventually forming water 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 Da. 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 chemical 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 at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the soil. In cases where inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified polymer may partition to the supernatant water, which is expected to be released to the sewer. Under a worst case scenario it is assumed that 50% 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 to be 29.77 µg/L [PEC_{river} = 134.62 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC is well below the EC₅₀ for algae of the most toxic anionic polymers (EC₅₀ > 1 mg/L).