

File No PLC/777

28 August 2008

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

FULL PUBLIC REPORT

Polymer in Digiprime 4431

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 legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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FULL PUBLIC REPORT**Polymer in Digiprime 4431****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Plastral Pty Ltd (ABN 68 000 144 132)
130 Denison Street
Hillsdale NSW 2036

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical Name, CAS Number, Molecular and Structural Formulae, Polymer Constituents and Residual Monomers/Impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Not known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Digiprime 4431

CAS NUMBER

Not assigned

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	13,639 Da
Weight Average Molecular Weight (Mw)	52,074 Da
Polydispersity Index (Mw/Mn)	3.8
% of Low MW Species < 1000 Da	2%
% of Low MW Species < 500 Da	< 1%

REACTIVE FUNCTIONAL GROUPS

Functional Group	Category	Equivalent Weight (FGEW)
Amine	High Concern	> 6500

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:	White/blue liquid
Glass Transition Temperature	Two glass transition temperatures are observed for the notified polymer; -61°C and -40°C to 70°C.
Density	Approximately 1100 kg/m ³ at 20°C (Estimated value based on similar polymers)
Water Solubility	Not determined. Low water solubility is expected based on the mainly hydrophobic structure of the notified polymer.
Dissociation Constant	pKa is estimated to be 4.4 based on the value of a component monomer, in which the dissociable functionality is maintained after being incorporated into the notified polymer.
Reactivity	The notified polymer contains hydrolysable functionalities. However, hydrolysis is unlikely to occur in the environmental pH range of 4 – 9.
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>
Tonnes	< 1	< 1	< 1	< 1	< 1

Use

A component in primer coating for use in the digital printing industry.

The notified polymer will be imported as a component (approximately 6.6%) of the product Digiprime 4431. Digiprime 4431 is intended for use as a primer coating in the digital printing industry, its function is to enhance the adhesion of digital images to paper and plastic film substrates. Digiprime 4431 will be applied using a roller coating machine, it will be picked up by a roller from a bath, transferred to another roller and then transferred from this roller to the substrate.

Mode of Introduction and Disposal

The notified polymer will not be manufactured or reformulated within Australia.

The notified polymer will be imported by sea through the port of Melbourne, as a component of the product Digiprime 4431, in 18 kg plastic pails.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

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

Occupational Health and Safety Risk Assessment

Dermal, and ocular exposure may occur during transfer of the product containing the notified polymer into the roller coating machine, maintenance and cleaning. However, exposure to significant amounts of the notified polymer is limited given the use of engineering controls and personal protective equipment by workers (safety goggles and gloves).

Although exposure to the notified polymer could occur during filling, coating and cleaning of the roller coating machine, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

Public Health Risk Assessment

The notified polymer will not be available for use by the public. Members of the public may come into contact with products containing the notified polymer. Once the primer dries, the notified polymer would be trapped in the printed paper, and therefore dermal exposure to the notified chemical from contact with the dried primer is not expected. Therefore, the risk to public health will be negligible because the notified polymer is of low hazard, and exposure is expected to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. Based on the monomer constituents, the notified polymer contains some anionic groups that are considered moderately toxic to algae but would not be applicable to this polymer. It may also contain potential cationic functionalities that are of high concern to aquatic species. However, the notified polymer has a molecular weight of over 10,000 and FGEW of > 5000.

Environmental Risk Assessment

The majority of the notified polymer will be bound to paper or plastic substrates through the application process, and be disposed of to landfill together with the substrates, be subject to slow degradation into small molecules through biotic and abiotic processes.

Based on its reported use pattern, the notified polymer is not considered to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

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

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

Environmental risk assessment

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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 of to landfill.

Emergency procedures

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

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 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 in primer coating for use in the digital printing industry, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 1 tonne, or is likely to increase, significantly;
 - if 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 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 MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.