

File No PLC/663

17 October 2006

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

FULL PUBLIC REPORT

Polymer in PU5

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full 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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	5
6.1. Exposure Assessment	5
6.2. Toxicological Hazard Characterisation	5
6.3. Human Health Risk Assessment	5
7. ENVIRONMENTAL IMPLICATIONS	5
7.1. Exposure Assessment	6
7.2. Environmental Hazard Characterisation	6
7.3. Environmental Risk Assessment	7
8. CONCLUSIONS	7
8.1. Level of Concern for Occupational Health and Safety	7
8.2. Level of Concern for Public Health	7
8.3. Level of Concern for the Environment	7
9. MATERIAL SAFETY DATA SHEET	7
9.1. Material Safety Data Sheet	7
10. RECOMMENDATIONS	7
10.1. Secondary Notification	8

FULL PUBLIC REPORT**Polymer in PU5****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Toxikos Pty Ltd (ABN 30095051791)

293 Waverly Rd

Malvern East, Vic 3145

NOTIFICATION CATEGORY

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, Polymer Constituents, Residual Monomers/Impurities, Spectral data, Use Details, Import Volume

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

None known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in PU5

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10000

METHODS OF DETECTION AND DETERMINATION

METHOD	IR spectroscopy and NMR spectrometry
Remarks	Reference spectra were provided

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</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

The notified polymer is not isolated from solution. Limited physico-chemical data have been provided for the product PU5 containing 10-30% of the notified polymer

Appearance at 20°C and 101.3 kPa	Pale yellow liquid
Melting Point/Glass Transition Temp	Not available. The polymer is not isolated from solution
Density	Not available. The polymer is not isolated from solution
Water Solubility	100 mg/L at 20°C The notified polymer is provided as an aqueous solution. Solutions at <100 mg/L in the aquatic toxicity testing were clear, though some white suspended particles were visible at 100 mg/L.
Dissociation Constant	The polymer contains functional groups that will completely dissociate in water except at lower pH.
Reactivity	The notified polymer is stable over the pH range of 3 to 9. It will not hydrolyse in the environmental pH range 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>
<i>Tonnes</i>	<20	<20	<20	<20	<20

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The polymer will be imported as a component of printing ink in a 775 mL cartridge container containing <1% of the notified polymer. It will be imported by ship and transported by rail or road to customer sites.

Reformulation/manufacture processes

The notified polymer is not manufactured or reformulated in Australia. It will be imported in closed cartridge containers ready for use.

End users (office workers or service technicians) will remove ink-jet or laser cartridges from their wrapping and replace a spent cartridge in the printer as necessary.

Use

The notified polymer is used as a component of printing ink for use in ink-jet printers in business applications. Future use in laser printers is also possible.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and possibly inhalation exposure of office workers and maintenance engineers to <1% of the notified chemical could potentially occur when replacing spent cartridges and clearing paper jams from the printer. Once the ink dries, the chemical would be trapped in the printed paper and will not be bioavailable. Therefore dermal exposure to the notified polymer from contact with the dried ink is not expected.

In the case of accidental spillage the quantity of ink released would be small (typically < 50 mL) and can be readily wiped up with a rag or tissue. The ink is not classified as a hazardous substance and no special training, or workplace controls are necessary for workers handling the cartridges other than to follow instructions accompanying the cartridge.

PUBLIC EXPOSURE

The notified polymer is intended only for use in commercial environment and as such public exposure to the notified chemical is not expected. Exposure from spillage during transport is not likely because ink containing the notified polymer is within a cartridge.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the product PU5 containing 10-30% notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >2000 mg/kg bw	no	no	OECD TG 423
2. Rabbit, skin irritation	slightly irritating	no	Yes*	OECD TG 404
3. Rabbit, eye irritation	Non irritating	no	Yes**	OECD TG 405
3. Skin sensitisation -LLNA.	no evidence of sensitisation.	no	no	EU Method B42 (LLNA)
4. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

* Erythema grade 1 was observed in all three animals up to 24 hours after treatment.

** Conjunctival redness was observed 1 hour after treatment in 2/3 animals. Conjunctival discharge was observed one hour after application in one of these two animals.

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during [maintenance and repair of printers](#), the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

PUBLIC HEALTH

The notified polymer is intended for use in commercial environment only, and will not be sold to the public. Following application, the notified polymer will not be bioavailable. Therefore, public exposure to the notified polymer is considered very low.

Even if some accidental exposure of the members of the public occurs, the risk to public health presented by the notified polymer is expected to be low due to its intrinsic low toxicity, and low concentration, <1% in the ink.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release of ink to the environment is not expected under normal use as the ink cartridges are designed to prevent leakage. If leakage or spillage does occur, it will be contained with absorbent material and disposed of with normal office garbage, ultimately to landfill. Residues within print cartridges may contain <1% of imported volume of the notified polymer, which would also be disposed of with normal office garbage, ultimately to landfill.

Virtually all of the notified substance will eventually be released to the environment. Most (>99%) will be bound to printed paper which will ultimately be buried in landfills, incinerated or undergo repulping in the pulp and paper recycling industry. When disposed of to landfill, the notified chemical is expected to remain attached to the treated paper.

In the paper recycling process, paper is repulped using a variety of chemical treatments which result in fibre separation and ink detachment from the fibres. The majority of the notified substance will end up in the resultant sludge with some being released in the effluent from the de-inking processes. This effluent is expected to be released to trade waste sewers. It is estimated that approximately 50% of the ink printed on paper will enter paper recycling and up to 60% of the ink is recovered during the recycling process."

It is estimated that approximately 50% of the ink printed on paper will enter paper recycling and up to 60% of the ink is recovered during the recycling process.

Using a worst-case scenario* 6 tonne of the notified chemical per year will be discharged to sewer with very little attenuated within these systems. Losses in sewage treatment plants is expected to be low given the low volatility and high water solubility of the chemical. Most of the inflow concentration of the notified chemical may potentially remain in solution, passing through the sewage treatment plant. The resultant estimated worst case PEC can be calculated as follows:

Amount released to sewer	6 tonnes
average value for water consumption	200 L/person/day
Australian population approx.	20 million
Number of days used	365
PEC _{sewer}	<u>6000000000</u>
	365x200x20000000
	= 0.0041 mg/L = 4.1 µg/L
PEC _{inland} (dilution 1:1)	4.1 µg/L
PEC _{ocean} (dilution 1:10)	0.41 µg/L

However the release of the polymer is expected to spread diffusively throughout Australia.

*This is calculated as 60% of (50% of 20 tonnes)

ENVIRONMENTAL FATE

The overall fate of the ink (and therefore the notified polymer) is either to landfill where it will slowly undergo abiotic degradation or by recycling, where the ink will be released from the paper and may enter fresh and marine surface waters.

7.2. Environmental Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in screening tests conducted on the notified polymer (for which only summaries were provided).

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Daphnia Toxicity	EC50>100 mg/L	no	Other: Brixhan Environmental Laboratory Standard Operating Procedure BA283.
Algal Toxicity	EC50 >100 mg/L	no	Other: Brixhan Environmental Laboratory Standard Operating Procedure BA285.

From the very brief notes provided it appears that the methods used were similar to the OECD TG 202 and TG 201.

All results were indicative of low hazard.

7.3. Environmental Risk Assessment

From the ecotoxicity data provided, the EC₅₀ value of >100 mg/L can be used to give a PNEC of >0.1 mg/L (100 µg/L), using a safety factor of 1000 since data for only two trophic levels is available. The risk quotient (RQ) can be estimated by PEC/PNEC, ie $4.1 / >100 = <0.041$. Based on the estimated RQ it is expected that the polymer will not pose a risk to the environment when used in the proposed manner.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is Negligible Concern to public health when used in the proposed manner.

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. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. 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.

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.
- 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

- Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- The notified polymer should be disposed of in landfill.

Emergency procedures

- Spills/release of the notified polymer should be contained and absorbed with sand or absorbent material. The used absorbent material, containing the notified polymer, should be placed in a labelled, sealable container ready for disposal to landfill.

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.