

File No SAPLC/78

January 2008

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

FULL PUBLIC REPORT

Polymer in PWL 5044X1

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 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 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 PWL 5044X1****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

H. B. Fuller Company Australia Pty. Ltd. (ABN 37 003 638 435)
 16-22 Red Gum Drive
 DANDENONG SOUTH, Victoria 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, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Customer Sites and Import Volume.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

USA – Pre-Manufacturing Notice (2001)
 Canada – New Substance Notification (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

PWL 5044X1

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) > 10,000 Da

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

Appearance at 20°C and 101.3 kPa	White liquid (product containing notified polymer).
Glass Transition Temp	2 ±2 °C
Density	1.03 (specific gravity of adhesive product)
Water Solubility	The notified polymer is dispersible in water.
Dissociation Constant	Not expected to dissociate in water. However, based on the known properties of the anionic functional group, the pK _a can be estimated at > 4.6.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

Comments

The polymer is not isolated from the adhesive formulation at any stage throughout its useful life.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED POLYMER (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>	10-30	10-30	30-100	30-100	30-100

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer is imported as part of a finished adhesive product at a concentration of approximately 20% of the final product by sea freight in 20 L plastic pails.

The adhesive product containing the notified polymer will be transported by road or rail to the notifier's warehouses before distribution to customer sites.

Manufacture processes

The final adhesive product, containing approximately 20% of the notified polymer, will be distributed to the two customer sites as imported.

At the customer sites, the adhesive product is poured into holding tanks located near the manufacturing line machinery. The manufacturing line process is fully automated and involves the use of high speed labelling machines which automatically apply the adhesive to the label before the label is attached to the PET (polyethylene terephthalate) bottle. The adhesive is then cured; the curing process usually just involves drying the adhesive.

Holding tanks and any contaminated equipment may be cleaned by flushing them with warm water. Wastewaters are processed through on-site wastewater treatment.

Use

The notified polymer will be used as a component of a label adhesive product to be used in automated high-speed labelling machines for labelling bottles for commerce. The notified polymer is only expected to be used and manufactured in industrial settings.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Storage and transport workers are unlikely to become exposed to the notified polymer, as it is imported in securely sealed plastic pails, indicating that worker exposure is only probable in the unlikely event of a transport accident where the storage containers have been severely damaged and pail contents spilt.

Most of the manufacturing process is automated and thus only a few workers would be handling the adhesive formulation, therefore the frequency of worker exposure will be low.

During formulation workers decant the product into holding tanks. Workers will wear impermeable gloves, eye protection and overalls. Exposure to the notified polymer may occur via the dermal and ocular routes however, significant exposure is limited due to workplace practices and PPE.

A fault on the manufacturing line or a product spill may potentially lead to worker exposure. This exposure would be minimised through the use of chemical resistant gloves, protective eye wear and overalls. All personnel would be adequately trained in the appropriate handling of the notified polymer or adhesive product and in the containment of spillages; a MSDS will be readily available to all relevant personnel.

PUBLIC EXPOSURE

The general public are unlikely to come into contact with the notified polymer as it imported as part of a formulation and will be manufactured in enclosed industrial settings. The label adhesive containing the notified chemical will be applied between a plastic PET bottle and the product label and will be cured onto the bottle before public sale of the product. The public may come into contact with the notified polymer if the label is accidentally or intentionally removed. In such a case, the notified polymer will be immobilised within the adhesive and would not be available for dermal absorption.

Adequate measures and controls are in place to minimise the risk of public exposure resulting from the spill or release of the notified polymer during manufacturing use, disposal or accidental spillage during transport and storage.

6.2. Toxicological Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to have insignificant health impact.

6.3. Human Health Risk Assessment

The OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer. The notified polymer is of high molecular weight and has the potential to cause lung overloading. However, the notified polymer is imported in a finished product and inhalation exposure to the adhesive is unlikely. Therefore it is not expected to pose an unreasonable risk.

The notified polymer will be part of an adhesive product that is cured prior to public sale, hence the notified polymer will not be available for dermal absorption. Under normal circumstances the public should not come into contact with the notified polymer. Based on the above and its use pattern, there is negligible concern for public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Residues of the notified polymer may remain in storage containers, however these will be cured before being disposed of to landfill; approximately 1% of the total import volume is expected to remain in storage containers.

Spills may also be an environment release point for the notified polymer. Spills will be adequately contained and collected for disposal to landfill; an estimate of 1% of the total import volume for the notified polymer can be attributed to spilled wastes. The notified polymer is imported as part of an adhesive formulation and constitutes approximately 20% of the product formulation. Any release from spills will likely result in a very small volume of the notified polymer released to the environment.

The notifier claimed that at some sites washings from cleaning tanks will be isolated and processed through on-site wastewater treatment.

ENVIRONMENTAL FATE

The environmental fate of the notified polymer is highly dependent on the biodegradability of the final product to which it is attached (i.e. plastic bottle). PET bottles are likely to end up in landfill at the end of their useful life in which case the notified polymer is expected to degrade over time. PET bottles can also be recycled; the recycling process involves the separation of the plastic granules from foreign matter including the product labels. In this case the notified polymer will still be disposed of to landfill as part of the product label.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

7.3. Environmental Risk Assessment

The notified polymer is imported as part of a label adhesive formulation at approximately 20% of the final formulation. Any release of the adhesive product as imported will be adequately contained and collected before appropriate disposal to landfill.

The plastic bottle end product will most probably be disposed of to landfill after the end of its useful life. However, it may be recycled in which case the label will be disposed to landfill. Very little if any will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC).

If the notified polymer is released uncured into the aquatic environment, it is not expected to be water soluble and therefore will not dissociate to any significant extent. It is likely to partition out of the water column where it would degrade over time.

Based on the exposure levels and use pattern, the notified polymer is unlikely to pose an unacceptable risk to the environment.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is No Significant 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, 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.

- 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.
- A copy of the MSDS should be easily accessible to relevant employees.

Disposal

- The adhesive product containing the notified polymer should be disposed of to landfill and should not be released to waterways.

Emergency procedures

- Accidental spills/release of the notified polymer in the adhesive product should be handled by containment with inert absorbent materials and safely collected into containers for adequate disposal to landfill.

11. 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.
 - The notified polymer is introduced in particulate form.

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from use as component of a label adhesive product (to be used in automated high-speed labelling machines for labelling bottles for commerce), or is likely to change significantly;
 - the amount of chemical being introduced has increased from 100 tonne per annum, or is likely to increase, significantly;
 - [if 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.