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

FULL PUBLIC REPORT

Polymer in Rapidex NP 2075 T

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 Sustainability, Environment, Water, Population and Communities.

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
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FULL PUBLIC REPORT**Polymer in Rapidex NP 2075 T****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

H.B. Fuller Company Australia Pty Ltd (ABN: 37 003 638 435)
16-22 Red Gum Drive
Dandenong South, VIC 3175

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1000 Da.

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, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Melting Point, Density, Vapour Pressure, Water Solubility, Hydrolysis as a Function of pH, Partition Coefficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Rapidex NP 2075 T (<60% notified polymer)

MOLECULAR WEIGHT

>1000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

One hazardous impurity/residual monomer (see below) is present at a level above the concentration cut-off for classification.

<i>Chemical Name</i>	Benzene, 1,1'-methylenebis[4-isocyanato- (MDI)
<i>CAS No.</i>	101-68-8 <i>Weight %</i> <10
<i>Hazardous Properties</i>	R40(3); Xn; R20-R48/20 Xi; R36/37/38 R42/43 Conc. \geq 25%: Xn; R40; R20; R48/20; R36/37/38; R42/43; \geq 10% Conc. <25%: Xn; R40; R48/20; R36/37/38; R42/43; \geq 5% Conc. <10%: Xn; R40; R36/37/38; R42/43; \geq 1% Conc. <5%: Xn; R40; R42/43; \geq 0.1% Conc. <1%: Xn; R42.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: off-white solid*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	ca. 160 °C*	MSDS.
Density	1020 kg/m ³ at 20 °C*	MSDS.
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low. Vapour pressure of residual MDI is 0.066 hPa at 20 °C.
Water Solubility	Not determined	Not tested due to the presence of isocyanate end-groups that readily react with water. Expected to have low water solubility, based on its predominantly hydrophobic chemical structure and high molecular weight.
Hydrolysis as a Function of pH	Not determined	Not tested due to the presence of isocyanate end-groups that readily react with water. The core of the notified polymer contains groups that are expected to hydrolyse only very slowly in the environmental pH range (4 – 9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the octanol phase based on its expected low water solubility.
Adsorption/Desorption	Not determined	Likely to sorb to sludge, soil and sediment based on its expected low water solubility and high molecular weight.
Dissociation Constant	Not determined	Contains no dissociable functions.
Particle Size	Not determined	Waxy solid.
Flash Point	Not determined	Flash point of residual MDI is 196 °C
Autoignition Temperature	Not determined	Not expected to autoignite based on melting point.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

*Rapidex NP 2075 T containing <60% notified polymer

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer contains reactive isocyanate functional groups. It is designed to react with atmospheric moisture as a part of the curing process, producing carbon dioxide. Hazardous polymerisation may occur at temperatures above 204 °C.

Dangerous Goods classification

Based on the limited submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will be introduced as a component of Rapidex NP 2075 T (<60% notified polymer).

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>	≤100	≤100	≤100	≤100	≤100

PORT OF ENTRY

Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS

Following its introduction into Australia, the notified polymer will be used in manufacturing processes at various commercial sites across the country.

TRANSPORTATION AND PACKAGING

The notified polymer will be supplied in 180 kg steel drums. The drums will then be transported within Australia by road.

USE

The notified polymer will be used as a component (<60%) of polyurethane hot-melt adhesive for the bonding of various substances, including wood, metal, glass, textiles, leather, polyurethane foams, membrane films and plastics.

OPERATION DESCRIPTION

The notified polymer will not be reformulated in Australia. Upon delivery to commercial sites, the drums containing the notified polymer (<60%) will be moved from the storage area to the application unit and the seal of the drum/pails will be broken under a vented hood. A plunger from the melter unit will be inserted into the drum and the drum moved into an enclosed melter. The melter will be set to the appropriate temperature to facilitate the delivery of the molten adhesives to the application head, which will then be applied to the substrate in a controlled manner as a molten bead. After 5 - 25 seconds another substrate will be laid on top of the initial one, sandwiching the adhesives. Complete cure of the adhesives will typically take up to 3 - 4 days depending on the temperature and humidity conditions. During curing, the articles will be stored in ventilated warehouse areas. Finished articles that have been bonded with the adhesive will then be distributed to retail outlets.

At the end of the melting process, the adhesive feed to the application head will be stopped and the remaining adhesive melt allowed to run to the tray below the application head and cured overnight. The applicator roller is coated with cleaning agents and allowed to remain overnight. The cured adhesives are removed for disposal to landfill on the following day.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	100	1	200
Application operators	100	6	100
Cleaning and maintenance workers	50	0.5	100
Finished Good Quality Inspector	50	2	40

EXPOSURE DETAILS

Transport and storage workers are not likely to be exposed to the adhesive products containing the notified polymer (<60%) except in the event of an accident.

Dermal exposure of the worker to the notified polymer may occur during its transfer to the melter. However, such exposure is expected to be minimised by the use of a fume extraction system and the use of personal protective equipment (PPE), including nitrile gloves, safety glasses with side shield, and coveralls. Inhalation

exposure is not expected to occur at this stage as the adhesives are solid blocks or waxy solid pellets and volatile components are not expected to be released.

Exposure of workers to the notified polymer (<60%) is not expected during melting and delivery to the application head of the adhesives as it takes place in an enclosed and automated system that is confirmed via a computer monitor that relays information about molten adhesive egress through a bleeder valve at the top of the melter plunger.

Inhalation exposure of workers to the notified polymers during application of the molten adhesives to the substrate is expected to be minimal as the process is automated and takes place under a ventilation hood to remove volatile components of the adhesives. In addition, aerosols are not expected to be formed. Dermal exposure to the notified polymer may occur when workers handle the bonded articles prior to curing. Such exposure is expected to be minimised by these workers wearing gloves and overalls. Once cured the adhesives will be inert and not bioavailable.

Cleaning and maintenance workers are expected to wear organic vapour filter masks, goggles, gloves, protective overalls and safety footwear to avoid dermal, ocular and inhalation exposure. If it is determined that a significant amount of the notified polymers and residual monomers remains uncured at this stage, cleaning workers are expected to wear air-line respirators or self-contained breathing apparatus complying with Australian Standard AS 1716.

6.1.2. Public exposure

The notified polymer is intended for industrial use only, therefore the public may be exposed to the imported product (<60% notified polymer) only in the event of a transport accident. The public will come into contact with manufactured products containing the cured adhesive. However, as the notified polymer will be cured and crosslinked to form an inert matrix, it will be unavailable for exposure.

6.2. Human health effects assessment

No toxicity data were submitted. In the absence of toxicological data on the notified polymer, the known general hazards of isocyanates have been considered, in particular, the hazards associated with MDI (benzene, 1,1'-methylenebis(isocyanato-); a residual monomer of the notified polymer).

Based on the high molecular weight (>1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the polymer contains a significant proportion of low molecular weight species (25% with MW <1000 Da) that may be absorbed.

Isocyanates are considered highly reactive and are known to be hazardous to human health. The main hazards posed by isocyanates include respiratory sensitisation in the form of asthma, as well as decreased respiratory function with the possibility of interstitial fibrosis and pulmonary oedema (Tillman, 2007). Isocyanate exposure is the most common cause of occupational asthma around the world (Mapp *et al.*, 1988; Bernstein, 1996) and no specific treatment is available for individuals who are sensitised. Individuals with a history of respiratory conditions such as asthma and hay fever may be more likely to develop isocyanate sensitivity (NOHSC, 1990). Polymeric isocyanates are less volatile and contain less free isocyanate, and are therefore expected to be less of an inhalation hazard. However, the UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing respiratory sensitisation similar to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray-mists could cause adverse respiratory effects (HSIS, 2008). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA 2010).

Isocyanates may be irritating to the skin and eyes and splashes in the eyes may lead to severe chemical conjunctivitis (NOHSC, 1990). In addition isocyanates may cause skin sensitisation from repeated or prolonged exposure (Kirk-Othmer, 1995). Although the potential for these effects is likely to be reduced due to the high molecular weight of the notified polymer, the presence of low molecular weight species means that these effects cannot be ruled out.

Health hazard classification

Based on the presence of the isocyanate functional group in the notified polymer, the notified polymer is

classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:.

Xn; R42 May cause sensitisation by inhalation.

The notifier has classified the imported product containing the notified polymer in the MSDS based on residual monomer, with the following risk phrases:

Xn; R40(3) Limited evidence of a carcinogenic effect.

Xn; R42/43 May cause sensitisation by inhalation and skin contact.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Workers that are exposed to isocyanates may have a concentration-dependent risk of developing respiratory diseases such as bronchial asthma (Baur *et al.*, 1994) and often the only treatment for sensitised individuals is to completely remove the worker from the workplace to avoid exposure (Bernstein, 1996). Therefore, measures should be in place to avoid workers from developing sensitisation. The engineering controls in place to reduce the exposure to vapours of the adhesives, such as the enclosed melter, the local exhaust ventilation during the binding process, and the ventilation during curing, are expected to minimise any potential inhalation exposure to the notified polymer. As the cleaning activities will be carried out after leaving the residual adhesives overnight the majority of the residual adhesives is expected to be cured. Cleaners are also expected to wear PPE including an organic vapour filter mask or an appropriately fitted air-line respirator or self-contained breathing apparatus complying with Australian Standard AS 1716 (NOHSC, 1990) if significant amounts of the notified polymer or residual monomers remain uncured. Such respiratory protection should also be used as deemed appropriate, during other handling procedures involving the notified polymer. In summary, the risk to workers of developing respiratory sensitisation is not considered unacceptable assuming that the stated engineering controls and proposed PPE are used.

The potential for the notified polymer to cause skin sensitisation, as well as skin and eye irritation cannot be ruled out. Dermal and ocular exposure may occur during the opening of the packages containing the solid notified polymer, handling of articles bound with uncured resin, or during the cleaning of equipment. However, this exposure is expected to be minimised by the PPE worn by the workers, including nitrile gloves, coveralls and safety glasses.

The imported product is melted at 155 - 175 °C. The MSDS for products containing the notified polymer indicate that hazardous polymerisation may occur above 204 °C. Therefore, provided the melting process is adequately controlled, any hazardous polymerisation should be avoided.

Therefore, when used under the conditions described the notified polymer is not expected to pose an unacceptable risk to workers.

6.3.2. Public health

The notified polymer is intended for use in industrial applications by qualified operators. The public may be exposed to products manufactured using the polymer-containing adhesive. However, the polymer will be cured and unavailable for exposure. Therefore, when used in the proposed manner, the risk to public health is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a component in ready-to-use polyurethane hot-melt adhesive. The notified polymer will not be manufactured or reformulated in Australia. Accidental spills during transport are expected to be collected, cured and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The formulated adhesive containing the notified polymer is used in commercial settings to bond various substrates including paper, metal and plastics. Molten adhesive is applied to articles in an enclosed and automated system. The adhesive will cure on exposure to atmospheric moisture and, once cured, will form a solid inert matrix. The majority of the notified polymer will be irreversibly cross-linked into the inert matrix. Up to 2% of the annual import volume of notified polymer is expected to be released to landfill as waste collected from the cleaning of manufacturing equipment and the residue remaining in empty import containers. The residues of the formulated product will be allowed to cure before disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be applied to the surfaces of articles as adhesive and will share the fate of the articles. At the end of their useful life most of the articles will be sent to landfill. Additionally, some substrates such as paper and metal may be sent to recycling facilities.

7.1.2 Environmental fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be disposed of to landfill as waste from the cleaning of manufacturing equipment, residues in empty import containers, and articles at the end of their useful life. Small quantities of notified polymer in adhesive on paper or metal substrates may be sent to paper recycling or metal reclamation facilities. On exposure to atmospheric moisture the hot-melt adhesive containing the notified polymer will slowly cross-link to form a solid inert resin matrix. Once cured, the notified polymer is irreversibly bound into the resin matrix and is not expected to be mobile or bioavailable. During paper recycling processes, the cured adhesive containing the notified polymer is expected to partition to sludge, and subsequently be disposed of to landfill. The notified polymer will eventually degrade biotically or abiotically in landfill, or by thermal decomposition during metal reclamation, to generate water and oxides of carbon and nitrogen.

The release of the notified polymer to the aquatic environment is not expected based on its reported use pattern. In the unlikely event of release to sewer or surface waters, the notified polymer would be removed from the water column by sorption to sediment and sludge. As its molecular weight is >1000 Da, it is not expected to cross biological membranes and, therefore, it is not likely to bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment is not expected based on its reported use pattern.

7.2. Environmental effects assessment

No ecotoxicological data were submitted. The notified polymer is a non-ionic polymer which is a solid at ambient temperature. In the presence of moisture, the notified polymer has the potential to become a cationic polymer, due to the presence of water-reactive isocyanate end-groups. Whilst cationic polymers may pose a concern for the aquatic environment, cationic polymers that are solids are of low concern (Boethling & Nabholz, 1997). Therefore, as the notified polymer is a solid, with no expected significant aquatic exposure, it is not expected to pose a concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified chemical as no significant aquatic exposure is expected based on its reported use pattern.

7.3. Environmental risk assessment

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for the notified polymer has not been calculated as release to the aquatic environment is not expected based on its reported use pattern as a component in ready-to-use polyurethane hot-melt adhesive (industrial use only). The majority of the notified polymer will be disposed of to landfill as cured adhesive. In the cured adhesive the notified polymer is irreversibly bound into a solid inert resin matrix, and is unlikely to be bioavailable or leach in this form. Due to its limited environmental exposure, the risk of the notified polymer to the environment is expected to be low based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the information provided, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrase:

Xn; R42 May cause sensitisation by inhalation

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	<i>Hazard category</i>	<i>Hazard statement</i>
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Human health risk assessment

Under the conditions of the occupational settings described where sufficient controls are in place to minimise inhalation exposure when necessary, 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

On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
 - Conc. \geq 1%: R42 may cause sensitisation by inhalation
- As the polymer is a Type 1 Ingredient, the applicant should ensure that the labels for products containing the polymer are acceptable to the relevant state authority.

Health Surveillance

- As the notified polymer contains isocyanate functional groups, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of isocyanate sensitivity, asthma or other pulmonary condition and who may be adversely affected by isocyanate exposure.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
 - Ventilation system including local exhaust ventilation.
 - Automated processes, where possible.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Keep containers securely sealed and check regularly for spills and leaks.
 - Avoid inhalation of vapours, mists and aerosols.
 - Avoid contact with skin.
 - Wash hands after handling the notified polymer, or containers and equipment containing it.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Gloves
 - Overalls
 - Safety glasses
 - Appropriately fitted air-line respirators or self-contained breathing apparatus complying with Australian Standard AS 1716 for cleaning and maintenance workers.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Atmospheric monitoring should be conducted to measure workplace concentrations of volatile adhesive components during use of the notified polymer. The Safe Work Australia exposure standard for isocyanates is 0.02 mg/m³ (TWA) and 0.07 mg/m³ (STEL).
- The melting temperature should be adequately controlled so as to avoid the formation of hazardous polymerisation products.
- A copy of the MSDS should be provided 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.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
 - Check all containers against leakage and ensure lids and caps are tightly sealed.
 - Store in a ventilated and bunded area.
 - Store in a cool, dry place away from direct sunlight.
 - Store away from acids, alkalis or amines.

Emergency procedures

- Spills 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 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 polymer has a number-average molecular weight of less than 1000;
 - the polymer is imported in a mixture that can be aerosolised;

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component (at <60%) in ready-to-use polyurethane hot-melt adhesive, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the 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 MSDS of the products containing the notified polymer provided by the notifier were reviewed by NICNAS. The additional risk and safety phrases assigned based on the concentration of hazardous impurities/residual monomers were noted. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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