

File No PLC/734

April 2008

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

FULL PUBLIC REPORT

Mylbond 110

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 Water Resources.

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**Mylbond 110****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Henkel Australia Pty Ltd
135-141 Canterbury Road
Kilsyth VIC 3137

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, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, and Manufacture/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)

Mylbond 110

OTHER NAME(S)

Modified starch

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >100,000 Da

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met
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:	Odourless white to off-white powder
Melting Point/Glass Transition Temp	The notified polymer is expected to undergo thermal degradation at 200°C.
Density	400– 600 kg/m ³ (loose bulk density of the powder) 500– 750 kg/m ³ (compacted bulk density)
Water Solubility	The notified polymer is a hot water soluble starch and therefore not soluble in water at temperature below 60°C.
Particle Size	Mean = 14-16 µm < 5 µm = 7.77% 5-10 µm = 16.70% 10-20 µm = 54.80% 20-40 µm = 20.72%
Reactivity	Stable under normal environmental conditions.
Degradation Products	The notified polymer contains linkages that may hydrolyse under extreme pH. However, significant hydrolysis is unlikely to occur in the environmental pH range of 4-9
When heated to decomposition temperatures, the notified polymer may release carbon oxides and irritating fumes.	

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	1	2	3	4	5
Tonnes	< 5	< 5	< 5	< 5	< 5

Use

The notified polymer will be used in labelling adhesives, especially for use on glass bottles.

The powder containing the notified polymer will be manually transferred from bags to a mixing vessel. Other components will be added and mixed with the powder to manufacture an adhesive product which contains 4-5% of the notified polymer. The adhesive formulation is mechanically filled into 15-1000 kg pails (or CB5 containers) or into polyethylene bags, which are then distributed to customers by road or rail. At the customer sites, the adhesive product is poured into the holding tanks before being used in the fully automated and high speed labelling machinery which applies the adhesives to the bottles before the label is stuck on. The bottles are then cured for a maximum of eight hours in order for the labels to adequately stick to the bottles.

Mode of Introduction and Disposal

The notified polymer will be imported neat as odourless white to off-white powder in 15-20 kg polyethylene bags.

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.

The notified polymer is in powder form and the notifier states that the particle sizes of the powder are <5 to 40 µm, with a mean of 14-16 µm. The powder is therefore comprised of inhalable particle sizes (<100µm), with a significant proportion in the respirable range (<10µm). The notified polymer is a high molecular weight insoluble polymer, and the inhalation of respirable particles of this class of polymer has been linked with irreversible lung damage (US EPA). This is expected to be a physical effect; i.e. deposition of particles to the deep lung from where they cannot be removed by normal clearance mechanisms. This may lead to lung overloading at higher exposure levels. Normal lung clearance mechanisms are expected to tolerate low exposures to the notified polymer.

There is no information available with regard to the health effects of inhalation exposure to the notified polymer. However, the inhalation of dusts generated by the notified polymer may be irritating to the mucous membranes and the respiratory system, and could include irritation arising from deposition of water-insoluble particles in the deep lung.

Occupational Health and Safety Risk Assessment

Transport and Storage

Dermal, ocular and inhalation exposure to the notified polymer may occur in the event of accidental breaching of the bags.

Formulation and Application

Repeated dermal and ocular exposures to the notified polymer may occur in the formulation process, however, these can be minimised by using appropriate personal protective equipment (PPE) such as overalls, rubber gloves and safety glasses with side shields. The primary risk to the occupational health of workers will be from the inhalation exposure to powders of the notified polymer. For the activities described, EASE modelling gives a predicted dust exposure of 2-5 mg/m³ (assuming dry manipulation of non-fibrous dust in the presence of LEV). However, these levels should only be present for short periods when powders are transferred to the mixing vessel, and during the cleaning and maintenance of equipment and work areas. The risks should be minimised by the proposed PPE such as appropriate particulate respirator and the provision of local exhaust ventilation in areas where exposed powders of the notified polymer will be handled. Worker exposure to the notified polymer after contact with the stuck on labels is negligible since the polymer is cured and is therefore unavailable for exposure.

The Australian recommended exposure standard for nuisance dust is 10 mg/m³ [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

Based on the expected low exposure to the notified polymer the risk to occupational health and safety is considered to be low.

Public Health Risk Assessment

The notified polymer will not be sold directly to the public. The public will be potentially exposed to the notified polymer in the form of the adhesive product contained between the label of a commercial product and the product packaging (e.g. glass bottle). However, in this state, the notified polymer will be cured and unavailable to cause any risk to public health. Although the public will be exposed to the glass bottles with stuck on labels containing the notified polymer, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Release

The majority of the notified polymer will be bound within the self-adhesive labels. There may be some release to the sewer from washing the holding tanks with water. 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 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. Due to its high molecular weight, it is not expected to bioaccumulate.

Environmental Risk Assessment

The notified polymer will be used as an adhesive. The notified polymer 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 or recycled at the end of their useful lifetime. In landfill it is expected that the notified polymer will remain immobile within the soil. During recycling glass is heated to about 1800°C and the incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

A very small quantity of the notified polymer is expected to be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC).

The above considerations indicate minimal risk to the environment when the notified polymer is used in the manner and levels indicated by the notifier.

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 the public.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations**CONTROL MEASURES****Occupational Health and Safety**

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in powder form:
 - Use of Local Exhaust Ventilation when handling the notified polymer in powder form
 - Avoid the formation of airborne dusts
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during certain processes where dust may be generated:
 - Use of particulate respirator when handling notified polymer in powder form and during cleanup operations
- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced in powder form
 - The level of atmospheric nuisance dust should be maintained as low as possible. The ASCC exposure standard for atmospheric dust is 10 mg/m³ but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”.

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 to landfill.

Storage

- Store indoors in a cool dry, and well ventilated area.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by transferring the spilled material to sealable containers and dispose in accordance with relevant state and federal requirements.

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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a labelling adhesive, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 5 tonnes, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way 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 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.