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

PUBLIC REPORT

Polymer in MOR-FREE™ L716 FB

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1782	Rohm & Haas Australia Pty Ltd and Dow Chemical Australia Pty Ltd	Polymer in MOR-FREE™ L716 FB	ND*	≤ 300 tonne/s per annum	Adhesive in food packaging material

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R42: May cause sensitisation by inhalation

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational setting, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

Based on its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
 - R42: May cause sensitisation by inhalation

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

- Due to the sensitisation properties of the notified polymer, the notifier should consider their obligations under the Australian Dangerous Goods Code.

Health Surveillance

- As the notified polymer is a skin/respiratory sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
 - Enclosed and automated systems
 - Local and general exhaust ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid skin and eye contact during operations
 - Clean any spills promptly and appropriately
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced: Overalls, impervious gloves and safety glasses

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 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 polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if

- the function or use of the polymer has changed from adhesive in food packaging material or is likely to change significantly;
- the amount of polymer being introduced has increased, 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 (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS

Rohm and Haas Australia Pty Ltd (ABN: 29 004 513 188)
Level 17, 8 Exhibition Street
MELBOURNE VIC 3000

Dow Chemical Australia Pty Ltd (ABN: 72 000 264 979)
Level 17, 8 Exhibition Street
MELBOURNE VIC 3000

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ 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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, 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: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANTS

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME

Polymer in MOR-FREE™ L716 FB

MOLECULAR WEIGHT

Number Average Molecular Weight (M_n) > 1,000 Da

ANALYTICAL DATA

Reference GPC and FT-IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 97%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer is stable under standard operating conditions and no loss of monomers, reactants, additives or impurities is expected.

DEGRADATION PRODUCTS

Not expected to occur under normal condition of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Amber clear viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	not determined	Viscous liquid at ambient temperature. The viscosity would limit the fluidity at low temperature.

Boiling Point	Not determined	Expected to undergo cross-linking and decompose before reaching the boiling point
Density	1,140 kg/m ³ at 20 °C	(M)SDS*
Vapour Pressure	< 1.3 x 10 ⁻⁹ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Not determined	The notified polymer contains groups that readily react with water to form carbon dioxide and insoluble high molecular weight polymers
Hydrolysis as a Function of pH	Not determined	The notified polymer contains groups that readily react with water to form carbon dioxide and insoluble polymeric masses.
Partition Coefficient (n-octanol/water)	Not determined	Expected to react with water and octanol to form carbon dioxide and insoluble polymeric masses.
Adsorption/Desorption	Not determined	The notified polymer contains groups that readily react with water to form carbon dioxide and insoluble polymeric masses.
Dissociation Constant	Not determined	Contains no dissociable functional groups.
Flash Point	>100 °C at 101kPa	(M)SDS*
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* For product containing the notified polymer at 70% concentration.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer will react with moisture in the atmosphere when container is opened. The pot-life for the polymer when in contact with atmospheric moisture is approximately one day.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. The notified polymer will be imported as a component of a two part polyurethane adhesive system. It will be imported in part A (MOR-FREE™ L716 FB, 70% notified polymer) in 20 L pails or 205 L drums.

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

Year	1	2	3	4	5
Tonnes	50–300	50–300	50–300	50–300	50–300

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer will be imported and distributed to customers by road in either 20 L pails or 205 L lined steel drums.

USE

The notified polymer will be used as an adhesive to laminate flexible polyolefin films including low density polyethylene, oriented polypropylene, nylon, aluminium, polyester and other packaging substrates.

OPERATION DESCRIPTION

At the customer's site, the product containing the notified polymer (part A) will be pre-mixed with part B in a ratio of 100:45 (A:B) and will be applied as a thin continuous film to one substrate in a commercial laminating / printing machine using a solvent free gravure method. The substrate is carried along a series of rollers, and then the adhesive side is pressed onto a second substrate, bonding the two substrates together. The individual parts of the adhesive system will be pumped directly from the imported containers into the laminating / printing machine and mixed in-line before being applied at approximately 40 °C. At the food processing site, the laminated film with the notified polymer cured in-between the two layers of laminate will be formed into packaging material, filled with the food product and sealed.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehouse workers	0.5 – 2	12 – 14
Machine operator	8	260
Packaging line operator	8	260

EXPOSURE DETAILS

Transport and warehouse workers are not expected to be exposed to the notified polymer ($\leq 70\%$ concentration) except in the unlikely event of an accident where the containers are breached.

Laminating machine operators may experience dermal and ocular exposure to the notified polymer ($\leq 70\%$ concentration) during transfer processes and during cleaning and maintenance of equipment. When the laminated film has been collected onto the finishing roller, the adhesive will be in a cured form sandwiched between the two layers of substrate and will not be available for exposure. The notifier anticipates that workers will wear personal protective equipment (PPE) such as overalls, safety boots, safety glasses, hard hats and impervious gloves to minimise exposure. A high degree of automation with local fume extraction at the coating station is also expected to reduce the exposure.

6.1.2. Public Exposure

The notified polymer is intended for use in industrial settings and will not be sold to the public. The public may come into contact with packaging material which was made using the notified polymer. However, the notified polymer will be trapped between layers of packaging material and cured into an inert solid and hence will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were provided for the notified polymer. However, it is a polymer that is expected to contain reactive isocyanates / diisocyanate functional groups which are known to be hazardous. Diisocyanates are well known dermal and inhalation sensitisers in the workplace and have been documented to cause asthma, lung damage, and in severe cases, fatal reactions (US EPA 2011). Apart from the concern for irritation and pulmonary toxicity (Barrett 1994, US EPA 2010, Kirk-Othmer 1995), isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010).

As in the case of the notified polymer, polymeric isocyanates tend to be non-volatile and are therefore expected to be less of an inhalation hazard compared to non-polymeric isocyanates. However, aerosols of polymeric isocyanates may cause 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 may cause adverse respiratory effects (HSIS, 2008).

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The notified polymer contains isocyanate functional groups. According to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), substances containing isocyanate functional groups should be classified as hazardous if there is no evidence to indicate that the substance does not cause respiratory hypersensitivity. Therefore, the following risk phrase should apply to the notified polymer:

R42: May cause sensitisation by inhalation

Although not considered in this assessment, it is acknowledgeable that, based on the MSDS provided, the imported MOR-FREE™ L716 FB, containing $\leq 70\%$ notified polymer, carries the following risk phrases due to the presence of other hazardous ingredients:

R20 – Harmful by inhalation

R36/37/38 – Irritating to eyes, respiratory system and skin

R40 – limited evidence of a carcinogenic

R42/43 – may cause sensitisation by inhalation and skin contact

R48/20 – Harmful: danger of serious damage to health by prolonged exposure through inhalation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer contains reactive isocyanate functional groups which are known to be hazardous and cause potential irritation and sensitisation to the skin and respiratory system. Control measures are required to mitigate possible adverse health effects to the workers who may come into contact with the notified polymer.

According to the MSDS of the product containing $\leq 70\%$ notified polymer, the product is classified as hazardous and dangerous due to the presence of other ingredients. Control measures taken against these hazardous ingredients would also reduce the health risk of the notified polymer posed to the workers. The notifier states that workers will wear overalls, safety boots, safety glasses, hard hats and impervious gloves during the operations. Closed and automated systems along with local exhaust ventilation will also be used to minimise potential inhalation exposure.

Provided that control measures stated by the notifier are in place, the risk to the health of workers from the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer is intended for use in industrial settings and will not be sold to the public. The public may come into contact with the notified polymer when handling packaging manufactured using the notified polymer. At this stage the notified polymer will be unavailable for exposure since it will be sandwiched between two impervious layers of film and cured into an inert solid. The notifier has stated that the notified polymer meets the USA 21CFR 175–105 indirect food contact packaging adhesive requirements (21CFR175.105).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Therefore, no release of the notified polymer to the environment is expected from this activity. If release does occur as a result of an accident during transport, it is expected to be contained, collected and expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Adhesives containing the notified polymer are expected to be applied to the food packaging in automatic laminating machines operated by professional operators. It is estimated that up to 2% of the total annual import volume of the notified polymer is expected to be released to the environment due to wastes from spills and leaks. The notified polymer in these wastes is expected to cure to an inert solid on exposure to ambient conditions and the cured mass is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be incorporated in a polymer matrix and bound to the surface of the food packaging after application. It is expected to share the fate of the packaging and be disposed of to landfill.

Residual notified polymer in empty import containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

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 cured waste, residues in empty containers, and adhesive on packaging materials at the end of their useful life. The notified polymer will be irreversibly cross-linked into a solid polymer matrix as part of its normal use pattern and is therefore not expected to be mobile, bioavailable or readily biodegradable in this form. The notified polymer is expected to eventually degrade biotically or abiotically in landfill into water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not determined because release of the notified polymer to the aquatic environment is not expected based on its reported use pattern as a component of an adhesive. Furthermore, if released in water the notified polymer rapidly reacts with moisture (water) to form insoluble, non-bioavailable, high molecular weight solids.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer is not expected to persist in water due to its hydrolytic instability. In addition, the notified polymer which is never isolated from the adhesive, reacts with water to form insoluble, non-bioavailable, high molecular weight solids. Therefore, the notified polymer is expected to be of low concern to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicological data for the polymer were submitted and the notified polymer is expected to be of low concern to the aquatic organisms.

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 of an adhesive. The majority of the notified polymer is expected to be disposed of to landfill as cured matrix. The notified polymer is irreversibly bound into a solid inert matrix, and is unlikely to be bioavailable or mobile in this form. Therefore, based on its expected low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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