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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Adcote 37P295HV

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 National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9 AM to 5 PM Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

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Director Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Polymer in Adcote 37P295HV

1. APPLICANT

Rohm and Haas Australia Pty Ltd of 4th Floor, 969 Burke Road, Camberwell, Vic 3124 and Coates Brothers Australia Pty Ltd of 323 Chisholm Road, Auburn, NSW 2144 have jointly submitted a limited notification statement in support of their application for an assessment certificate for **Polymer in Adcote 37P295HV**.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Polymer in Adcote 37P295HV

The presence of monomeric and dimeric forms of the notified polymer (acid form) was identified in the molecular weight analysis of the notified polymer.

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physico-chemical properties are for the polymer solution Adcote 37P295HV, unless otherwise stated.

Appearance at 20°C & 101.3 kPa: White milky fluid.

Boiling Point: 100°C (aqueous solution, boiling point of water)

Specific Gravity: ~0.98

Vapour Pressure: Not volatile.

Water Solubility: Completely soluble.

Partition Co-efficient

(n-octanol/water): Not determined; likely to partition into aqueous phase

due to high water solubility.

Hydrolysis as a Function of pH: Not determined, does not contain functional groups

which might hydrolyse under environmental pH

conditions (4-9).

Adsorption/Desorption: Not determined, due to high water solubility will be

mobile in soils. At pH <5, the polymer will revert to carboxylic acid form which will be less mobile in soils.

Dissociation Constant: Not determined, as the notified polymer is likely to

dissociate significantly to the less soluble acid form

under acidic conditions (pH<5).

Flash Point: Not determined.

Flammability Limits: Not determined.

Autoignition Temperature: Not determined.

Explosive Properties: Not determined.

Reactivity/Stability: Not determined.

4. PURITY OF THE CHEMICAL

Degree of Purity: Unknown

5. USE, VOLUME AND FORMULATION

The notified polymer is intended for use in a 'one pack' laminating adhesive for polymer and/or aluminium films used in snack food packaging and other general packaging. The polymer will be imported as a 5% component of Adcote 37P295HV in an aqueous solution. Adcote 37P295HV will be imported into Victoria in 20L plastic pails and sold to customers. No further formulation will occur in Australia. The adhesive is applied by a gravure coating process where two films are laminated together and the adhesive is sandwiched between them.

The estimated quantity of the notified polymer in Adcote 37P95HV to be imported is < 10 tonnes in the first 5 years.

6. OCCUPATIONAL EXPOSURE

Transport and storage

The notifier has estimated that 5 waterside workers and 5-10 transport and warehouse workers will be involved in the transport and storage of the product containing the notified polymer. These workers could be exposed to the notified chemical only in the event of an accident where the packaging is breached.

Laminating machine operator

At the laminating site, Adcote 37P295HV is decanted manually into an adhesive tray below the laminating machine rollers. The blended adhesive is applied by the gravure coating process where two polymers films are laminated together with the adhesive between the films. Following completion of a run, unused adhesive in the laminating machine tray or reservoir is transferred back to adhesive pail for reuse at a later time. The adhesive residues on the machinery are washed off manually using rags and water.

There will be 10-15 laminating machine operators who may be exposed to the product containing the notified polymer and the blended adhesive. The maximum potential exposure for laminating machine operators is estimated to be 6-8 hours per day, 50 days per year. The main routes for occupational exposure to the polymer will be through skin and eye contact. Inhalation exposure to the notified polymer will not be significant due to its low volatility. Laminating machinery operators wear safety glasses, impervious gloves, overalls and safety boots during transfer of the adhesive to laminating machines, and cleaning of the machines. Laminating machinery is fitted with exhaust ventilation ducts either above the adhesive tray or in a wall or ceiling adjacent to the machinery.

Workers at the packaging factories will handle the laminated material and packed dry food where the notified polymer is unavailable for absorption.

7. PUBLIC EXPOSURE

Public exposure to the polymer solution will be limited to accidental spillage. The notified polymer will enter the public domain in packaging for food and general items. Consequently, public exposure to the packaging is likely to be high, but contact with the notified polymer in a dried adhesive layer sandwiched between two layers of polymer film is likely to be limited.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The polymer will be stored in undercover warehouses at the importer and customer sites, protected by bunding to contain accidental spills.

There is potential for spillage of the polymer solution to occur during the transfer and use of laminating adhesives. It will be contained within the plant through bunding. There is little emission risk to the atmosphere as the polymer is not volatile. Any residues or spills will be cleaned up with absorbent material and taken off-site by a licensed industrial waste contractor for disposal to landfill. The notifier estimates that around 1% of the notified polymer solution (dependent on customer usage) may be lost to spillage in this manner, at each customer site. Therefore, if an import rate of <10 tonnes is assumed, <100 kg of the polymer will be lost in this manner.

At the end of each laminating run, any unused polymer solution will be transferred back to pails for reuse. The notifier estimates that approximately 1 kg of polymer solution residue may remain on machinery and the adhesive tray. These residues will be wiped off with rags dampened with water and disposed of with industrial waste. The waste will then be disposed of to landfill by licensed waste contractors. The notifier estimates that, based on use at 50

days per year per site at 5 customer sites, approximately 250 kg of polymer solution containing 12.5 kg of the notified polymer will go to landfill by this route.

Pails containing residual polymer solution (approx 100 mL/pail) will be disposed of to landfill. The notifier indicates that the majority of residue will have dried to a solid mass by the time the empty pails reach landfill. Based on the maximum import rate of <10 tonnes per annum, < 50 kg of notified polymer per annum will go to landfill from this route.

The majority of the notified polymer (>90%) will share the fate of the packaging material substrates to which it is adhered. Used packaging material will mainly be disposed to landfill, but some may be incinerated, or carelessly disposed into the environment.

Overall, it is estimated that < 160 kg of the notified polymer will be disposed to landfill from the manufacturing and machinery cleaning phases, and the disposal of 'empty' pails. However, the bulk of the notified polymer will be disposed of to landfill as packaging product wastes.

8.2 Fate

The majority (90%) of waste from spills, cleaning and container residues will go to landfill and the majority of this portion (>80%) will reach landfill in a dry, solid form. Any polymer solution reaching landfill would be expected to dry or flocculate, and precipitate into soil within a few days. Upon drying, the polymer solution will become a flexible, slightly tacky solid. The notified polymer will become part of this solid containing hydrophobic waxes and polymers. Although the polymer salt is readily soluble in water, it is part of a mixture of resins and waxes, which are likely to be adsorbed to organic matter, and would not be expected to leach. However, it is possible that the presence of water could cause a portion of the polymer to redissolve. Upon dissolution in water and subsequent reduction in pH, the polymer is expected to revert to the carboxylic acid form, which has limited water solubility. This form of the polymer would associate with the soil matrix. The incineration of polymer waste would yield water, oxides of carbon, and sodium compounds within ash. The polymer is not expected to cross biological membranes due to its high molecular weight, and as such should not bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicology reports were submitted. Sensitisation effects have been reported in relation to the acid form of the notified polymer. The notifier indicates that a similar product has acute oral LD₅₀s of >3 g/kg, >4 g/kg, and >2.5 g/kg in mice, rats, and guinea pigs, respectively. In repeat-dose studies conducted in several species, decreased weight gain/weight losses and liver enlargement were observed. No-observable effects levels (NOELs) were 0.2-1% (in diet) in a 90-day oral study in rats and 0.05% (in diet) in chronic oral studies in rats and dogs.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Release of the notified polymer to the aquatic compartment is only likely in cases of spills. However, the majority of the notified polymer will share the fate of the products in which it is incorporated and eventually be disposed of in landfill. In landfill, the polymer is unlikely to be mobile in the soil environment and would be expected to very slowly degrade to gases such as carbon dioxide through abiotic and biotic processes. The environmental hazard of the notified polymer in landfill is expected to be low.

A major proportion of the notified polymer consists of a monomer which has a 96 hour LC₅₀ toxicity value of 0.41 mg/L for juvenile trout, thus classifying it as highly toxic towards fish. However, the notified polymer is unlikely to contain a significant fraction of free monomer and related acids. In addition, the likely low and diffuse nature of the release of the polymer to the aquatic compartment should greatly mitigate any risks associated with the polymer's release into waters.

The polymer's large molecular weight and expected low water solubility should prevent bioaccumulation (Connell, 1990).

Given the above considerations, the overall environmental risk is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

12.1 Hazard assessment

No toxicological data have been provided for the notified polymer. The notifier indicates the acid form of the notified polymer is a potential skin sensitiser. In the absence of data to the contrary, the notified polymer is classified as a skin sensitiser according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC) 1999. The following risk phrases are required for the notified polymer as well as the product, Adcote 37P295HV containing 5% notified polymer: R43 'may cause sensitisation by skin contact'.

12.2 Occupational health and safety

Dermal exposure to the polymer in Adcote 37P295HV may occur during the transfer of Adcote 37P295HV from the pails to laminating machines and when cleaning the laminating equipment. The predominant routes of exposure during these activities are via skin and eye contact. Significant inhalation exposure is not anticipated.

The product Adcote 37P295HV is a potential skin sensitiser, therefore skin and ocular exposure to the polymer solution must be stringently controlled. Laminating machine operators must wear safety glasses, impervious gloves, overalls and safety boots when handling Adcote 37P295HV. Local exhaust ventilation further minimizes exposure. Engineering controls and the protective clothing combined are adequate to minimize the health risk to laminating machine operators.

The notified polymer becomes unavailable for absorption once it is incorporated in the

laminated material. Therefore, the health risk for workers in the food packaging industry, and in the distribution and retailing snack food is considered to be negligible.

There is little potential for significant health risk to the notified polymer in the transport and storage of the product containing this polymer.

12.3. Public health

It is expected that public exposure to the notified polymer in its liquid state will be limited, except in the rare event of an accidental spill. The notified polymer will be encapsulated within an inert, very high molecular weight film matrix, rendering it biologically unavailable. Public contact with the notified polymer in packaging is further limited as the adhesive containing the notified polymer is sandwiched between two layers of polymer film, restricting any dermal contact. Consequently the health risk from exposure to the notified polymer through all phases of its life cycle is considered to be low.

13. RECOMMENDATIONS

Regulatory controls

- The following health hazard classification is determined for the notified polymer:
 - R43 'may cause sensitisation by skin contact'
- Use the following risk phrases for products/mixtures containing the notified polymer at >1%:
 - R43 'may cause sensitisation by skin contact'

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer in the product Adcote 37P295HV:
 - Exhaust ventilation ducts adjacent to laminating machines
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer in the product Adcote 37P295HV:
 - Safety glasses, impervious gloves, overalls and safety boots

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 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.

13.1 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 Section 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.

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the polymer solution Adcote 27P295HV was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REFERENCES

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC: 2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008 (1999)]. Australian Government Publishing Service, Canberra.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	Rating	Oedema Formation	Rating	
No erythema	0	No oedema	0	
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1	
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2	
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3	
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4	

The Draize scale (Draize et al., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	Rating	Area of Cornea involved	Rating
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	Rating	Chemosis	Rating	Discharge	Rating
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not	2 mod.	Obvious swelling with partial eversion of lids Swelling with lids half-	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
easily discernible Diffuse beefy red	3 severe	closed Swelling with lids half- closed to completely closed	3 mod. 4 severe	Discharge with moistening of lids and hairs and considerable area around eye	3 severe

IRIS

Values	Rating
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82: 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49: 2-56.