NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Dynapol P 1500

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

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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Table of Contents

SOIV.	TWIATE	4
CON	ICLUSIONS AND REGULATORY OBLIGATIONS	2
ASS	ESSMENT DETAILS	3
1.	APPLICANT AND NOTIFICATION DETAILS	3
2.	IDENTITY OF POLYMER	4
3.	PLC CRITERIA JUSTIFICATION	4
4.	PHYSICAL AND CHEMICAL PROPERTIES	4
5.	INTRODUCTION AND USE INFORMATION	5
6.	HUMAN HEALTH RISK ASSESSMENT	5
7.	ENVIRONMENTAL RISK ASSESSMENT	5

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1026	International Sales & Marketing Pty Ltd	Dynapol P 1500	No	≤20 tonnes per annum	Coating for the internal side of food cans and as a hot-melt adhesive
	The Valspar (Australia) Corporation Pty Ltd				

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

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

Health and Safety Recommendations

- Water insoluble high molecular weight polymers used in the respirable size range ($< 10 \mu m$) have the potential to cause lung overloading. Respiratory protection and local exhaust ventilation should be used to prevent inhalation exposure when powders containing the notified polymer are handled.
- 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.

Environmental Recommendations

 No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal

• The notified polymer should be disposed to landfill.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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 polymer, 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 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 notified polymer has changed from a coating for metal food cans or a hot-melt adhesive, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased per annum, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified 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 notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

International Sales & Marketing Pty Ltd (ABN 36 467 259 314) 262 Highett Road Highett VIC 3190

The Valspar (Australia) Corporation Pty Ltd (ABN 82 000 039 396) 13 Webber Parade East Keilor VIC 3033

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 and manufacture/import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

Dynapol P 1500

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 Off-white granules Melting Point/Glass Transition Temp 164-174°C

Density 1290 kg/m³ at 20°C

Water Solubility Not determined. The notified polymer is considered to be

insoluble in water due to its hydrophobic structure.

Particle Size The notified polymer (>99%) is in granular form. The

notified polymer when in formulated products (40-70%) is

in powdered form with 100% of particles $< 100 \mu m$.

Reactivity Incompatible with strong antioxidants, acids and bases.

Hydrolysis is unlikely to occur in the environmental pH range of 4-9 despite the presence of hydrolysable

functions in the notified polymer.

Migration A migration study was conducted with the finished product

containing the notified polymer (coating thickness $\sim 90\mu m$) to examine the migration potential to distilled H_2O (1h $130^{\circ}C$, 10d $40^{\circ}C$), 3% acetic acid (1h $130^{\circ}C$, 10d $40^{\circ}C$), 10% ethanol (1h $130^{\circ}C$, 10d $40^{\circ}C$), isooctane (2.5h $60^{\circ}C$, 2d $20^{\circ}C$) and n-heptane (2h $65^{\circ}C$), to simulate contact with different food types. The detected migrates were highest in acetic acid (4.5 mg/L). When the identity of migrates was examined, two monomers were identified in acetic acid (~ 0.1 mg/L), whilst they were undetectable following migration to distilled H_2O and to ethanol. The study concluded that the test material does not add to food any particles and/or components which are innocuous to human

health.

Degradation Products None expected under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

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

Year	1	2	3	4	5
Tonnes	<10	< 20	<20	<20	<20

Use

The notified polymer will be imported into Australia at a concentration of >99% and in formulated products between a concentration of 40 and 70%. The notified polymer will also be reformulated in Australia to a concentration of between 40 and 70%. The notified polymer will be used as a coating for the internal side of metal food cans (direct food contact) and may also be used as a hot-melt adhesive.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard.

The formulated product (40-70%) containing the notified polymer is in powdered form with 100% of particles <100 μ m. The portion of respirable particles (<10 μ m) is unknown but it is assumed that the formulated product will contain respirable particles. Given that the notified polymer is of high molecular weight and is insoluble, some concern exists for the inhalation of such particles, due to studies in which irreversible lung damage was linked to the inhalation of respirable particles such as polymers. 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.

Occupational Health and Safety Risk Assessment

Workers may be exposed to the notified polymer (40-70% concentration) as respirable particles during reformulation and when applying the formulated product by electrostatic methods. The expected use of dust masks and/or localized air extraction systems should reduce inhalation exposure levels and hence lower the risk of possible lung overloading.

Possible dermal and ocular exposure to the notified polymer is expected to be lowered by the use of personal protective equipment (PPE) such as coveralls, chemical resistant gloves and goggles when workers are handling the notified polymer. In addition, thermal gloves are expected to be worn when handling the formulated product during the hot melt application process.

The risk of the notified polymer to occupational health and safety is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

Public Health and Safety Risk Assessment

The main route of public exposure is likely to be from residues from the consumption of food contained in cans coated internally with the notified polymer. The notifier has indicated that the notified polymer has been approved for food contact use in the USA and EU. The submitted migration study showed that exposure is expected to be low. Given the assumed low hazard and the expected low public exposure, risk to the public is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

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

The notified polymer will be imported in reformulated products and also as the polymer for formulation into products in Australia for use in coating for the internal side of metal food cans and hot melt adhesives applications.

As common case scenarios, reformulation and the applications of the formulations are expected to be conducted in automated industrial processes by trained professional workers. Releases of the notified polymer may occur during reformulation and application processes due to potential spills and residues in empty containers, which are estimated to be up to 0.15% of the annual import volume of the notified polymer, and are expected to be disposed of to landfill.

The notified polymer will share the fate of the articles to which it has been applied. At the end of their useful life most of the articles will be sent to landfill. Additionally, some metal substrates may be sent to recycling facilities. In case any release occurs to the sewer, the notified polymer is expected to adsorb to the soil sediment and be sent to landfill, where is expected to be immobile due to its low water solubility. Therefore, the notified polymer is likely to degrade in landfill or by thermal decomposition to form water and oxides of carbon. Bioaccumulation is not likely based on the high molecular weight of the notified polymer and its limited potential for exposure to the aquatic environment when used as proposed.

Based on the proposed use pattern and low assessed hazard, the notified polymer is not expected to pose any unreasonable risk to the aquatic environment.