

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

EMA-GMA Polymer

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

This Public Report is 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 SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1388	The Valspar (Australia) Corporation Pty Limited	EMA-GMA Polymer	No	< 15 tonnes per annum	Component of coatings for food cans

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

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

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 of 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 polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- 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;
 - the notified polymer is intended to be used as a component of coatings in contact with beverages, beer or baby formula;
 - the notified polymer is intended to be used for food contact at a level exceeding 13% by weight of cured coatings;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of internal coatings for tinsplate steel food cans, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, 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 (M)SDS of the notified polymer and a product containing the notified polymer were provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant

The Valspar (Australia) Corporation Pty Limited (ABN 82 000 039 396)
L4, 2 Burbank Place
BAULKHAM HILLS NSW 2153

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 import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

EMA-GMA Polymer

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Clear liquid*
Melting Point/Glass Transition Temp	Not determined
Density	1,022 kg/m ³ *
Water Solubility	Expected to be low based on the high molecular weight and hydrophobic chemical structure
Dissociation Constant	Contains no dissociable functionalities
Particle Size	Imported in solution
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*For EMA-GMA polymer (containing the notified polymer at ≤ 10%)

5. INTRODUCTION AND USE INFORMATION

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>
Tonnes	< 5	< 15	< 15	< 15	< 15

Use

The notified polymer will not be manufactured in Australia. It will be imported at $\leq 10\%$ concentration in finished coatings in 200 L steel drums and will not be further reformulated and repackaged in Australia.

The notified polymer will be used as a component of internal coatings for tinplate steel food cans. The finished coatings will be applied at industrial sites only.

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. Although it contains a high concern functional group, it has a high molecular weight $>10,000$ Da and low levels of low molecular weight species < 1000 Da, which are expected to mitigate any hazard and risk to workers handling the coating containing the notified polymer at $\leq 10\%$. In addition the coating containing the notified polymer is classified as hazardous, and the consequent worker controls would reduce worker exposure to the notified polymer. The public will not be exposed to the polymer in uncured form.

The notified polymer will be used for direct food contact as a component of internal coatings for steel food cans. Once the coatings are cured and dried, the notified polymer will be bound into the matrix of the coatings and is not expected to migrate into the food at high levels. The notified polymer has been approved in the USA for specific food contact use at a level not to exceed 13% by weight of cured coatings, excluding use for beverages and infant formula. In Europe, the notified polymer has been approved for specific food contact use as an additive up to 25%, for contact with all types of foodstuffs except beer and beverages. In addition, there is a specific migration limit for one monomer in the food as set in the EU Regulation.

Analytical reports submitted by the notifier on the finished cured coating containing monomers or oligomers of the notified polymer (with NAMW $< 1,000$ Da) showed that the migration from the coating to 10% or 50% ethanol for various times at elevated temperatures was well below the global limit of the EU and US food contact legislations (10 and 8 mg/dm², respectively). The level of migration of a monomer with a specific migration limit in the EU was also low.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

The risk to workers when the notified polymer is used as proposed is not considered to be unreasonable. When used in accordance to overseas food contact approvals, the risk to public health is not considered to be unreasonable.

The public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information as food contact with the notified polymer may occur.

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 into Australia as a component of finished industrial coatings for tinplate steel food cans; no reformulation or repackaging will occur in Australia. Release of the notified polymer to the environment during import, storage, and transport is expected to be limited to

accidental spills or leaks. Spills or accidental release of the products containing the notified polymer are expected to be collected with adsorbents and disposed of to landfill in accordance with local government regulations.

Coatings containing the notified polymer will be applied by roller techniques in an automated industrial process. No significant releases to the environment are expected from this process, as the notified polymer is expected to be cured and immobilised on the metal surface. Solid wastes from residues in empty containers are expected to be collected and disposed of to landfill in accordance with local government regulations.

The notified polymer in industrial coatings cured on the substrate will share the fate of the coated article, which ultimately is expected to be disposed of to landfill, or undergo thermal decomposition during metal recycling. In landfill, the notified polymer will be present as cured solids, which will be neither mobile nor bioavailable. Based on its high molecular weight the notified polymer is not expected to cross biological membranes, and is therefore not expected to be bioaccumulative. In landfill and during substrate recycling, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

Therefore, based on its assumed low hazard, limited expected aquatic exposure and assessed use pattern in coatings for tinplate steel food cans, the notified polymer is not considered to pose an unreasonable risk to the environment.