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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Core-Shell Emulsion

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
The Valspar (Australia) Corporation Pty Ltd (ABN 82 000 039 369)
13 Webber Parade
East Keilor VIC 3033

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, Other names, Molecular formula, Structural formula, Molecular weight, Spectral data, Identity & weight % of hazardous impurities, Identity & weight % of adjuvants/additive, Purity, Use details, Manufacture/Import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point/Freezing Point, Boiling Point, Density, Water Solubility, Hydrolysis as a Function of pH, Partition Coefficient (n-octanol/water), Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Core-Shell Emulsion (product containing the notified polymer at <40%)

CAS NUMBER
Not assigned

MOLECULAR WEIGHT
Mn Value >10000 Da

ANALYTICAL DATA
A reference GPC spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
All hazardous impurities and residual monomers are present at levels below the concentration cut-offs for classification.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
The notified polymer is in dispersion with solvents (including 1-5% of 2-(dimethylamino)ethanol) that may result in irritation by inhalation and by contact with skin or eyes (R36/37/38).

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions of use.

DEGRADATION PRODUCTS
None under normal conditions.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: The notified polymer is manufactured in a dispersed medium and is never isolated from this medium. The formulation containing the notified polymer (<40%) is a milky liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Never isolated from a liquid dispersion
Boiling Point	Not determined	Expected to have high boiling temperature (>200°C), based on its high molecular weight
Density	Not determined	Never isolated from a liquid dispersion
Vapour Pressure	Not determined	Never isolated from a liquid dispersion
Water Solubility	Not determined	The notified polymer is expected to have low water solubility, based on its predominately hydrophobic structure and the manufacturer's empirical observations
Hydrolysis as a Function of pH	Not determined	The notified polymer is expected to hydrolyse very slowly over the environmental pH range (4–9) at ambient temperature
Partition Coefficient (n-octanol/water)	Not determined	The high molecular weight of the notified polymer indicates that it will not cross biological membranes
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to solids, based on its predominantly hydrophobic structure
Dissociation Constant	Not determined	The notified polymer is a salt but has low potential to dissociate in the environment
Particle Size	Not determined	Never isolated from a liquid dispersion
Flash Point	Not determined	Never isolated from a liquid dispersion
Flammability	Not determined	The notified polymer is not expected to be flammable
Autoignition Temperature	Not determined	Not expected to auto-ignite at ambient temperatures, based on the experience in use
Explosive Properties	Not determined	Not expected to be explosive, based on lack of explosive functional groups.

DISCUSSION OF PROPERTIES
Reactivity
The notified polymer is stable under normal conditions.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table, the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Initially, the notified polymer will not be manufactured in Australia and will be imported as a <40% component of a resin system used in the manufacture of beverage cans. The notifier has also stated that, in future, the notified polymer may be manufactured in Australia.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1000	<1000	<1000	<1000	<1000

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The Valspar (Australia) Corporation Pty Limited

TRANSPORTATION AND PACKAGING
The notified polymer will be initially imported in 200 kg steel drums by sea or airfreight into Sydney or Melbourne and transported by road to the customer site. The notifier has stated that, in future, the notified polymer may be imported in isotankers containing approximately 23,000 kg.

USE
The formulation containing the notified polymer (<40%) is intended to be used as a coating for beverage cans.

OPERATION DESCRIPTION
The notified polymer will be imported as a <40% component of a resin system used in the interior coating of beverage cans. The notifier has also stated that, in future, the notified polymer may be manufactured in Australia.

Manufacturing process
A monomer premix will be prepared in tank A and the remaining monomers will be mixed in tank B. Monomers will be added to the tanks via an automated and enclosed system. The water and catalyst are added via an automated and enclosed system and the monomers are reacted at 100˚C before being cooled and further reacted. Both tanks are enclosed to control the release of fumes and vapours. Most of the monomers react with each other and form a blend with the neutralized resin mixture. Further additives are added to the resin mixture to form the finished product containing the notified polymer.

Samples will be taken from a controlled sampling point at this stage for quality control testing by laboratory technicians. The finished product containing the notified polymer will be gravity-fed into drums from the bottom of the mixing vessel through a filter and filling lines. All manufacturing and application equipment will be cleaned by rinsing with water or solvent. All above processes will occur under exhaust ventilation.

Coating application in the manufacturing of beverage cans
The formulation containing the notified chemical at <40% (coating solution) will be transferred under exhaust ventilation to a reservoir via a mechanical decanting pump. The coating solution is then sprayed on to beverage cans using a fully automated process. For the coating process, beverage cans are first loaded onto the machine and the conveyer transports the beverage cans to the spray gun tips. The spray gun tips are then inserted into the beverage cans and the interior of the beverage can is sprayed with a film of the coating solution containing the notified polymer as the tip is withdrawn. The coating is then heat cured, which immobilises the notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and Storage	10	1	200
Manufacturing operations	4	7	24
Roller Coating Operations	30	4	220
Cleaning and Maintenance	10	1	200

EXPOSURE DETAILS

The most likely routes of exposure are dermal, accidental ingestion, mist inhalation, and ocular. Gas-phase inhalation exposure is not expected to be significant due to the very high molecular weight and the fact that the polymer is never isolated from a liquid.

Transport and storage workers are not expected to be exposed to the coating solution containing the notified polymer except in the unlikely event of an accident where the drums become breached.

Manufacturing process
Dermal, accidental ingestion, and ocular exposure to the notified polymer may occur during various processes involved in the manufacturing of the notified polymer. However, exposure to the notified polymer will be minimised by the use of an automated and enclosed system for mixing and reaction of monomers, a controlled sampling point, the use of gravity to fill drums, and the use of local exhaust ventilation and PPE. Enclosed tanks will also allow the control of possible release of fumes and vapours during the reaction of monomers at 100˚C. Overall, considering all of the above, significant exposure to the notified polymer during manufacturing process is expected to be limited.

Coating application
Dermal, mist inhalation and ocular exposure to the notified polymer may occur during certain processes involving the notified polymer, such as transfer of the notified polymer to a reservoir and/or the interior spraying of beverage cans. However, considering the use of a mechanical decanting pump, the use of an enclosed spraying system, and local exhaust ventilation, exposure is expected to be limited. Dermal, accidental ingestion, and ocular exposure may also occur from drips and spills during connecting and disconnecting hoses and during cleaning and maintenance of the equipment. The notifier has indicated that workers will wear personal protective equipment (PPE), such as overalls, protective eyewear, and gloves to minimise exposure to the notified chemical. Therefore, considering all the above, exposure to the notified polymer during coating application is not expected to be significant.

6.1.2. Public exposure
The product containing the notified polymer will not be sold to the general public, except in the form of finished beverage cans. Therefore, the general public will not be exposed to the notified polymer as such. There is potential for extensive public exposure to beverage cans containing the notified polymer. However, after the notified polymer has been cured, it will crosslink to form an inert coating and thus will be unavailable for exposure and is not expected to migrate into the beverages. Therefore, exposure to the general public is not expected to be significant.

6.2. Human health effects assessment

No toxicological data were submitted on the notified polymer. The notified polymer is not expected to be significantly absorbed from the gastrointestinal or respiratory tract, or via the skin, due to its high molecular weight (>10,000 Da), low proportion of low molecular weight species, and expected low water solubility.

Based on structural alerts, the notified polymer may present as an irritant. The irritancy potential is expected to be at most slight, given the high molecular weight and low proportion of low molecular weight species of the notified polymer.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
As toxicological studies were not submitted on the notified polymer for toxicological end-points, the hazard of the notified polymer is uncertain. However, based on structural alerts, irritancy is possible.

Limited exposure to the notified polymer may occur during various manufacturing and coating application processes. This is likely to be further reduced due to the enclosed systems and PPE expected to be worn when handling the notified polymer.

Given the low potential hazard, the proposed use of PPE and the engineering controls in place, the risk to workers using the notified polymer is assessed as being negligible.

6.3.2. Public health

Given that the public will not be exposed to the notified polymer in a bioavailable form, and that it is not expected to migrate into the beverages, the risk to the public is assessed as being negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

An estimated 1% of the annual introduction volume of notified polymer may be lost as result of spillages that occur during coating manufacture. The spillages will be absorbed with inert materials which will be collected and disposed of to landfill. A maximum of 1% of the imported notified polymer will remain in import drums as residues that will be collected by licensed waste contractors. The notified polymer in storage containers will be cured prior to disposal to landfill.

It is estimated that less than 1% of the notified polymer may be lost due to cleaning of the manufacturing equipment as the equipment will be washed with ether and may be released to the sewer treatment plants. However, these washes are expected to undergo a treatment whereby the notified polymer is removed and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The spray coater application is very efficient (approximately > 95 %) with any coating not applied (i.e. excess material) being retained and recycled or directed through a solvent recovery plant. The collected solids from this process are sent to landfill. Equipment cleaning and container residues will also account for some release of the polymer, which will be handled in the same manner as the application process. It is estimated that up to 2% of the introduced volume will be disposed of during coatings application and equipment cleaning and up to 1% of the introduction volume of the notified polymer will be disposed of during drum cleaning.

RELEASE OF CHEMICAL FROM DISPOSAL

Ultimately the final product to which the coating will be applied will either be recycled or go to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is expected to be cured into a solid polymer matrix as part of its normal use pattern and is not therefore expected to be bioavailable or biodegradable. The majority of the imported quantity of notified polymer is expected to be thermally decomposed during recycling of cans to which it is applied. Bioaccumulation of the uncured polymer is unlikely due to the high molecular weight of the notified polymer and its limited potential for aquatic exposure. Notified polymer disposed of to landfill is not expected to be mobile, and it will slowly degrade *in situ* primarily by abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present in significant concentrations in the aquatic environment because of its anticipated low water solubility and very low potential for direct release to surface waters when used in can coatings. A PEC has therefore not been calculated.

7.2. Environmental effects assessment

No ecotoxicity data for the notified polymer were submitted. Cationic polymers can pose a concern to aquatic organisms due to sorption to anionic biological membranes (e.g. gills). Whilst the core of the notified polymer contains cationic functionality, it is ionically bonded to, and encapsulated within, a polymeric shell. Therefore, no cationic sites are expected to be available to sorb to biological membranes and the notified polymer is not anticipated to pose a significant hazard to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicological data were submitted.

7.3. Environmental risk assessment

A Risk Quotient is unable to be quantified as a PEC and PNEC were not calculated. The reported use pattern of the notified polymer indicates that there is no anticipated aquatic release and the majority of the imported quantity of polymer will be destroyed during metal recycling. Hence, the environmental exposure is expected to be minimal. On the basis of the reported use pattern, the notified polymer is not expected to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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 public health.

Environmental risk assessment
On the basis of the reported use pattern, the notified polymer is not considered to pose an unacceptable risk to the environment.

Recommendations
CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to aerosols of the notified polymer during spray application:
  - Local Exhaust ventilation
  - Enclosed and automated systems

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product Polymer in Core-Shell Emulsion:
  - Chemical resistant gloves
  - Coveralls
  - 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 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 of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, 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 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(2) of the Act; if
- the function or use of the polymer has changed from a component of coatings for beverage cans, or is likely to change significantly;
- the amount of polymer being introduced has increased from 1000 tonnes, or is likely to increase, significantly;
- the method of manufacture of the polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the polymer on occupational health and safety, public health, or the environment;
- 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of a product containing 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.

BIBLIOGRAPHY

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.