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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Gold Epoxy Coating

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 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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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/1961	The Valspar (Australia) Corporation Pty Ltd	Polymer in Gold Epoxy Coating	ND	≤ 10 tonnes per annum	Internal coating for metal food packaging

^{*}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 of Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment

Under the conditions of the occupational settings described, 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.

As the notified polymer will be used in food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

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

- As no toxicity data for the notified polymer is available, 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 in the product Gold Epoxy Coating:
 - Protective goggles
 - Gloves
 - Coveralls
 - Protective shoes
 - Respirator where needed

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

- A copy of the 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.

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 Da;
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from internal coating for metal food packaging, 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.

Safety Data Sheet

The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

The Valspar (Australia) Corporation Pty Ltd (ABN: 82 000 039 396)

2 - 44 Graingers Road,

WEST FOOTSCRAY VIC 3012

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $Mn \ge 1,000$ Da.

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, migration data and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (TSCA), Canada (DSL), Korea (KECL) and Philippines (PICCS)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Gold Epoxy Coating (product containing the notified polymer)

OTHER NAME(S)

Durez 33386 (solution containing the notified polymer)

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark amber liquid with slight phenolic odour (solution containing the notified polymer).

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be imported and used in liquid formulations.
Boiling Point	Not determined	Expected to be high based on structure of the notified polymer
Density	$107.8 - 131.8 \text{ kg/m}^3$	SDS. Study not provided.
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer, the vapour pressure is expected to be low.
Water Solubility	Insoluble	The notified polymer is expected to have low water solubility based on its predominately hydrophobic structure
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 notified polymer is expected to partition from water to n-octanol on the basis of its low water solubility
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in

Dissociation Constant	Not determined	soil based on its high molecular weight and presence of cationic functionality which will adsorb to soil and sediment. Contains basic functionalities with a pka of 4-5
		which are expected to be protonated in the environmental pH range of 4-9.
Particle Size	Not determined	The notified polymer will be imported and used in liquid formulations.
Flash Point	Not determined	Imported in flammable mixture
Autoignition Temperature	Not determined	Imported in flammable mixture
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer polymerises on exposure to increased temperature.

Physical hazard classification

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

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia as a component of a coating solution.

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

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

PORT OF ENTRY

The notified polymer will be imported through the port of Melbourne.

TRANSPORTATION AND PACKAGING

Gold Epoxy Coating containing the notified polymer at a concentration of <10%, will be imported in 200 L steel closed head drums and transported by road to sites where the packages will be coated. The coated metal packages will be distributed by road to industrial customers as required.

Use

The notified polymer will be used in internal coating for metal food packaging.

OPERATION DESCRIPTION

The notified polymer will be imported into Australia as a component of a formulated finished coating at <10% concentration by weight. The finished product will be contained in 200 L steel drums and supplied in this manner to the notifier's customers. The notified polymer will not be used for reformulating purposes and will not be repackaged in Australia. The notifier's customers will apply the finished coating onto tinplate via roller coating in a well ventilated area. The plates are then cured in a thermal oven to achieve the required performance of the coating, and fabricated into cans. The cans are used as packaging for food.

5. HUMAN HEALTH IMPLICATIONS

5.1. Exposure Assessment

5.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Stevedores	2-3	10-15
Transport and warehousing/ storage workers	6	260
Personnel at the industrial customers site i.e., application	6	260
workers, maintenance workers, cleaners.		

EXPOSURE DETAILS

During transport and storage, direct exposure of workers to the coating containing the notified polymer at < 10% is unlikely, except in the case of accidental spillage.

It is anticipated that no manual handling of the finished coating will occur during application to tinplate or during fabrication of the coated cans. Applicators of the finished coating at the industrial sites may be exposed via the dermal or ocular routes. Maintenance workers and cleaners may also experience dermal and ocular exposure to residues of the finished coating when cleaning the application equipment and accidental spills or leaks from the work process. Exposure to these workers on site should be mitigated through the use of PPE such as goggles, gloves and other protective clothing. Inhalation exposure is not expected from the roller-coating process, unless aerosols are generated in the process. Local exhaust ventilation or respirators would be used where needed to control exposure.

Once the coating is dried and cured, the polymer will be incorporated into the coating matrix, and is not expected to be bioavailable. Therefore the potential for worker exposure during subsequent handling of the coated metal and cans is expected to be very low.

5.1.2. Public Exposure

The notified polymer within the finished product will be supplied only to the notifier's industrial customers. The public is therefore unlikely to be directly exposed to the notified polymer. Dermal exposure to the coating after opening of cans is expected to be very low.

The notified polymer will come into direct food contact as a component of internal coatings for metal food cans, and food could be a source of public exposure. 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. A report submitted by the notifier on the finished cured coating stated that all starting substances within the notified polymer were permitted for use in food packaging coatings according to the European Council of the Paint, Printing Ink and Colours Industry (CEPE) Code of Practice and Council of Europe Resolutions AP (2004) 1 and AP 92 (2), as well as the 21 CFR 175.300 of the US FDA Regulations. The report stated that the results of the migration study on the coating system, using aqueous and non-aqueous food simulants, were below the global limit of the EU and US food contact legislations and satisfied the food migration restriction requirements of Art. 3, Regulation (EC) No. 1935/2004 and 21 CFR 175.300 of the US FDA Regulations.

5.2. Human Health Effects Assessment

No toxicity data were submitted. Based on its high molecular weight (> 1000 Da), the potential of the notified polymer to cross the gastrointestinal tract or to be dermally absorbed after exposure is expected to be limited. However, the polymer contains a proportion of low molecular weight species (< 500 Da) that may be absorbed.

Health hazard classification

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

5.3. Human Health Risk Characterisation

5.3.1. Occupational Health and Safety

Toxicological information on the notified polymer is not available. Workers may experience accidental dermal and ocular exposure to the notified polymer during the transfer of the product, application process and equipment cleaning and maintenance. The use of PPE such as appropriate certified respirators, safety glasses with side shields, chemical resistant impervious gloves, chemical-resistant protective clothing and work boots will help mitigate dermal and ocular exposure and any inhalation exposure. In addition, the product in which the notified polymer is imported and used is hazardous. Workplace controls used to reduce exposure to other ingredients of the product will also reduce worker exposure to the notified polymer.

The notified polymer contains some hazardous impurities. However, these are present in the coating product at levels lower than the cut-off concentration for hazard classification.

Given the use of PPE and storage controls in place, the risk to workers from use of the notified polymer is not considered to be unreasonable.

5.3.2. Public Health

The product (Gold Epoxy Coating) containing the notified polymer at a concentration of < 10% will be only used in industrial settings and will not be sold to the public. The public may have dermal contact with the cured coating on cans after opening, however dermal exposure and the consequent risk to the public is expected to be very low.

The public may be indirectly exposed to the notified polymer through its use in food-contact coatings. A food migration study into aqueous and non-aqueous food simulants was provided by the notifier in support of the coating's compliance with overseas food contact regulations.

6. ENVIRONMENTAL IMPLICATIONS

6.1. Environmental Exposure & Fate Assessment

6.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of finished industrial coatings for metal food packaging; 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 absorbents and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

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. Wastes from residues in empty containers are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be 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.

6.1.2. 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 the notified polymer is expected to be thermally decomposed during recycling of metal food packaging to which it is applied. 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 and nitrogen.

6.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

6.2. Environmental Effects Assessment

No ecotoxicity data were submitted. However, it should be noted that some functional groups of the notified polymer would generate potentially cationic functionality which are considered a concern to aquatic organisms. However, this effect is not significant given no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

6.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the proposed use pattern.

6.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern as a coating for food metal packaging. The majority of the notified polymer will be disposed of to landfill as a cured polymer matrix in coated articles. The notified polymer bound in coated articles is unlikely to be bioavailable or mobile in this form. On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.