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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Ebecryl 444

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:

Street Address: Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.

TEL: + 61 2 8577 8800 FAX: + 61 2 8577 8888 Website: www.nicnas.gov.au

Director NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANTS	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1915	Akzo Nobel Pty Ltd & Allnex Australia Pty Ltd	Polymer in Ebecryl 444	ND*	< 1 tonne per annum	Component of coatings

^{*}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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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.

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed, automated processes, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with skin and eyes
- 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:
 - Coveralls
 - Protective gloves
 - Protective goggles

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.

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 importation volume exceeds one tonne per annum notified polymer;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of coatings, 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.

(Material) Safety Data Sheet

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANTS

Akzo Nobel Pty Ltd (ABN:59 000 119 424)

51 McIntyre Road

SUNSHINE NORTH VIC 3020

Allnex Australia Pty Ltd (ABN: 24 160 397 768)

Level 12, 680 George Street SYDNEY NSW 2000

NOTIFICATION CATEGORY

Limited-small volume: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year).

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, 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 APPLICANTS

None

NOTIFICATION IN OTHER COUNTRIES USA (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME

Ebecryl 444 (product containing the notified polymer at < 60% concentration)

MOLECULAR WEIGHT

> 500 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided

3. COMPOSITION

Degree of Purity > 97%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear to light amber viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at ambient temperature
Boiling Point	> 100 °C at 101.3 kPa	(M)SDS*
Density	$1,280 \text{ kg/m}^3$	(M)SDS*
Vapour Pressure	$< 1.33 \text{ x } 10^{-3} \text{ kPa at } 20 ^{\circ}\text{C}$	(M)SDS*
Water Solubility	8.9 g/L at 25 °C	Measured*
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionalities. However, no significant hydrolysis is expected to occur in the environmental pH range of $4-9$.

Property	Value	Data Source/Justification
Partition Coefficient	Not determined	Expected to partition from water to n-octanol
(n-octanol/water)		on the basis of its predominantly hydrophobic structure.
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight and predicted
		low water solubility.
Dissociation Constant	Not determined	Contains ionisable functionalities. Therefore,
		the notified polymer is expected to be ionised
		at the environmental pH range of $4-9$.
Flash Point	> 100 °C at 101 kPa	(M)SDS*
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that would
		imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would
- •		imply oxidative properties

^{*} For product containing the notified polymer at < 60% concentration

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted 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.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia either as a component of a product Ebecryl 444 (at $\leq 60\%$ concentration), or as a component of finished coatings for metal packaging (at $\leq 20\%$ concentration).

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

Year	1	2	3	4	5
Tonne	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF RECIPIENTS

Akzo Nobel Pty Ltd

Allnex Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of a product Ebecryl 444 (at < 60% concentration) for reformulation, and as a component of finished coatings (at < 20% concentration), in 205 L drums and in 2.5 to 10 kg metal tins, respectively.

Use

The notified polymer will be used as a component of UV-cured coatings for the external surfaces of metal packaging.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia.

Reformulation

The reformulation process will involve typical blending processes. The imported product containing the notified polymer at < 60% concentration will be transferred to a closed blending tank by the use of hose and pumping

equipment. The blending tank is expected to be in a bunded area and ventilated locally. After testing a sample for quality control, the finished coating will be pumped into various size containers (typically 10 kg tins) by the use of a filling machine, and distributed to end users.

End-use

Finished coating products containing the notified polymer (< 20% concentration) will be delivered to end-users (commercial metal sheet printing companies) from the port of entry, or from the reformulation site. Coatings will be manually transferred to coating tanks from coating containers, followed by sealing of the coating tank. The coating will be applied to the metal sheets using wet lithographic or dry offset printing processes in a largely enclosed and automated system. Once the coating has been deposited onto the metal substrate, UV light will cause rapid curing and cross linking of the notified polymer and other components in the coating, to form a solid print matrix. The printed metal sheeting will then be cut and formed into tubes/containers.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Transport and storage	4-8	50
Blending operators	8	12-24
Quality control/chemists and technical service	0.5-6	25
Printer operators	1-2	25
Service technicians	8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Reformulation

At reformulation sites, dermal or ocular exposure to the notified polymer (at < 60% concentration) may occur whilst opening containers, during connection/disconnection of hoses and during quality control testing. The potential for dermal and ocular exposure should be minimised by the stated use of PPE (goggles, impervious gloves, coveralls) by workers. Given the expected low vapour pressure of the notified polymer, inhalation exposure to the notified polymer is only expected during blending where aerosols may be generated. The stated use of enclosed blending vessels should mitigate the potential for inhalation exposure under these circumstances.

End-use

At end-use sites, dermal or ocular exposure to the notified polymer may occur during manual transfer of the finished coatings containing the notified polymer (at < 20% concentration) to the coating tanks. Exposure to the notified polymer is not expected during metal printing due to the automated and enclosed nature of the printing process. Once the coatings are cured, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.1.2. Public Exposure

Products containing the notified polymer (at < 20% concentration) are for industrial use only and will not be supplied to the general public. The public may be exposed to the cans/containers which have been coated externally with the coatings containing the notified polymer. Once the coatings are cured, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a number average molecular weight (NAMW) < 1,000 Da and contains a significant proportion of low molecular weight species < 500 Da, therefore absorption across biological membranes cannot be ruled out.

The notified polymer has been classified as a Category 2 Eye Irritant on the submitted MSDS for the product. This is consistent with the classification provided by companies to ECHA in CLP notifications.

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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

As no toxicological data are available for the notified polymer, the health hazards of the notified polymer cannot be determined. The notifier has classified the notified polymer as a Category 2 Eye Irritant. The notified polymer contains a significant proportion of low molecular weight species < 500 Da, therefore the potential for systemic effects cannot be ruled out. Given the uncertainty as to the hazard profile of the notified polymer, control measures should be in place to limit exposure.

During reformulation and printing activities exposure to the notified polymer is expected to be limited by the largely automated and enclosed processes, exhaust ventilation and stated use by the notifier of PPE including coveralls, impervious gloves and goggles. Once the coatings are cured, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The finished coating products containing the notified polymer are intended for industrial use only and will not be available to the public. The public may come into contact with metal items coated with the notified polymer. However, once the coatings are cured, the notified polymer will be bound within a polymer matrix and will not be available for exposure. Therefore the risk to the public from the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured; however, it will be reformulated in Australia as a component of coatings for the external surfaces of metal packaging. Reformulation of the notified polymer will occur in a closed system, therefore release to the atmosphere is expected to be negligible. Solvent used for equipment washing, containing residues of the notified polymer will be disposed of via accredited waste disposal contractors. During formulation activities approximately 1% of the notified polymer is expected to remain as residue in the empty containers. A further 1% may be lost as result of spills and equipment leaks. Material lost due to spills and leaks will be collected and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The reformulated coating formulation containing the notified polymer will be delivered to end-users. At customer sites, the coatings containing the notified polymer will be applied to the metal sheets in an enclosed and automated system. The notified polymer is likely to be stable within an inert matrix on printed substrate once UV-cured. Based on the application process, direct release to sewer is not anticipated. Any spills will be collected for disposal in accordance with local regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the coating articles to which they have been applied. The metal articles are expected to be disposed of to landfill or recycled. During metal recycling, the coating will be thermally decomposed to water and oxides of carbon and chlorine. Residues in empty containers containing up to < 1% of the notified polymer is expected to be disposed of to landfill in accordance with local regulations.

7.1.2. Environmental Fate

The majority of the notified polymer is expected to be incorporated into an inert matrix following its normal use as components in metal coatings. The notified polymer is not expected to be bioavailable nor biodegradable in this form. Notified polymer in solid waste disposed of to landfill is not expected to be mobile due to its limited water solubility and estimated high n-octanol/water partition coefficient, and soil adsorption coefficient. Significant amount of notified polymer is not expected to be released to the aquatic environment.

The notified polymer is not expected to rapidly degrade in landfill. However, bioaccumulation of the notified polymer is unlikely due to its high molecular weight and limited water solubility. The notified polymer will eventually degrade in landfill, or by thermal decomposition during metal reclamation processes, to form water, oxides of carbon and chlorine.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, which is not applicable to the notified polymer. Therefore, the notified polymer is not considered to be an over-chelation hazard to algae. The notified polymer is expected to present a low hazard to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

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.

BIBLIOGRAPHY

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

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 .