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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

ADDITOL® VXW 6208

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.

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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1877	Allnex Australia Pty Ltd Alchemy Agencies Pty Ltd	ADDITOL® VXW 6208	ND*	≤ 20 tonnes per annum	Additive in paints, coatings and pigment concentrates

^{*}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

Provided that the recommended controls are being adhered to, 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

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 as introduced in the product:
 - Enclosed and automated reformulation processes with local exhaust ventilation
 - Spray booths if spray applications occur
- 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 as introduced in the product:
 - Avoid contact with skin and eyes
 - Avoid breathing aerosols and mists
- 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 as introduced in the product:
 - Protective clothing/coveralls
 - Impervious gloves

- Eye protection
- Respiratory protection

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- 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 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 1,000;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from an additive in paints, coatings and pigment concentrates, 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 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

APPLICANT(S)

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

Level 12, 680 George Street SYDNEY NSW 2000

Alchemy Agencies Pty Ltd (ABN: 44 116 410 274)

Level 15, 60 Station Street PARRAMATTA NSW 2150

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

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

Korea

China (2013)

Taiwan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) ADDITOL® VXW 6208

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light brown liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	The notified polymer is supplied as an aqueous solution.
Boiling Point	Not determined	The notified polymer is supplied as an aqueous solution.
Density	$1,050 \text{ kg/m}^3 \text{ at } 20.0 ^{\circ}\text{C}$	(M)SDS
Vapour Pressure	Not determined	Expected to be $< 10^{-8}$ mmHg
Water Solubility	Not determined	The notified polymer is water soluble based on the presence of hydrophilic functionalities.

Hydrolysis as a Function of pH Partition Coefficient	Not determined	The notified polymer contains functional groups that are expected to hydrolyse slowly in the environmental pH range (4–9) at ambient temperature Due to high water solubility the notified polymer is
(n-octanol/water)	Tvot determined	expected to partition to the aqueous compartment.
Adsorption/Desorption	Not determined	Expected to partially adsorb to soil, sediment and sludge based on its high molecular weight
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	Not determined	Not expected to autoignite under normal conditions of use
Flammability	Not determined	Not expected to be flammable under normal conditions of use
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

DISCUSSION OF PROPERTIES

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 as a 50% aqueous solution in 205 L steel drums.

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

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

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will be received in Australia by the notifiers.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a 50% aqueous solution in 205 L drums and will be formulated into coatings and supplied in 20 L cans. The notified polymer will be stored in the import containers or coating cans (once reformulated).

Her

The notified polymer will be used as a pigment wetting and dispersing agent for waterborne coating systems. The notified polymer will be imported as a 50% aqueous solution and reformulated to a final concentration of 1.5–5% with inorganic pigments and 7.5–25% when used with organic pigments. The coatings will be used for industrial applications to primers on wood, metal, cement, concrete and plastic, or coatings for wood, metal, plastic and concrete. The reformulated end-use products containing the notified polymer will not be made available to the general public.

OPERATION DESCRIPTION

The notified polymer will be imported as a 50% aqueous solution for reformulation in Australia. Factory operators will be involved in transferring the notified polymer from 205 L steel drums into open stainless steel

blending tanks under local exhaust ventilation. High speed dispersion and mixing in covered pots is used to blend the coating components. Factory personnel will sample and test the imported polymer solutions and final coating formulations containing the notified polymer. The reformulated finished products containing the notified polymer will be filled from floor pots via the hoppers by gravity feed into 20 L steel cans. Each filling line will have a ventilation extraction system. The reformulated end-use coating products containing the notified polymer will be held in a warehouse prior to distribution to customers. Warehousing and distribution of the reformulated end-use products involves storing, loading and moving.

End use

The paint and coating products containing the notified polymer (at < 25% concentration) may be used in factory settings using spray booths and automated equipment or applied manually by professional tradespersons by airless spray, brush or roller.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and warehousing	1–2	12–24
Coating formulation	8	100
Application of coatings / End use	8	250

EXPOSURE DETAILS

Transport and warehousing

The notified polymer will be imported into Australia as a 50% aqueous solution in 205 L steel drums. Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Coating formulation

Worker exposure may occur during the reformulation of the notified polymer into the coating products, predominantly by the dermal route. Ocular exposure may occur in the case of accidental spillage. Inhalation exposure to the notified polymer is not expected due to low vapour pressure, low mist formation and the engineering controls employed (local exhaust ventilation and closed processes).

Workers involved in the reformulation of the notified polymer may be exposed dermally from accidental spillage or splashing during transfer of the notified polymer into the mixing vessel/apparatus. This may occur while connecting/disconnecting hoses or through splashes occurring during pouring.

Workers involved in quality assurance may be exposed dermally during sampling and testing of reformulated products containing the notified polymer.

Workers involved in the filling of containers with reformulated product may be dermally exposed to the notified polymer through drips or splashes occurring while filling containers. Workers will wear personal protective equipment including: overalls, safety boots, hard hat, safety glasses or face shield and impervious gloves.

End use

The coating products containing the reformulated notified polymer may be applied either as original equipment manufacturer (OEM) coatings in a factory setting using spray booths and automated equipment or applied manually by professional tradespersons. Manual application will involve tradespersons applying the coating by brush, roller or spray equipment. On completion of the coating application process, the operators will clean the equipment using paper and water.

6.1.2. Public Exposure

Paint products containing the notified polymer will not be sold to the public. The public may come into contact with surfaces coated with the paints containing the notified polymer. However, once the paints have dried, the notified polymer will be bound within the paint matrix and will not be bioavailable for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The SDS of a product containing the notified polymer indicates that it is of low acute oral and dermal toxicity (LD50 > 2,000 mg/kg) and inhalation toxicity (LC50 > 5 mg/L-4h) in rats, and not irritating to the eye or skin. The notified polymer contains structures that may degrade to release aromatic amines, which may be considered as an alert for skin sensitisation, mutagenicity and genotoxic carcinogenicity (Barratt *et al* 1994, Payne & Walsh 1994, Ashby & Tennant 1988).

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).

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers or impurities that are classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). Two of them are classified as R45/R46 – may cause cancer/may cause inheritable genetic damage and R40 – limited evidence of a carcinogenic effect respectively. However, these residual monomers or impurities are not present in the notified polymer, as introduced, above the cut off concentrations for classification.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer may have the potential to cause skin sensitisation and genotoxicity due to the presence of a relevant structural alert. Users of the notified polymer should be aware of the potential for such adverse effects when considering control measures for protection. However, the risk of the adverse effects from exposure to the notified polymer is expected to be limited by its high molecular weight (Mn > 1,000 Da with < 8% low molecular species).

During reformulation workers will be handling the notified polymer at concentrations up to 50%. During the end use workers may come into contact with the notified polymer at concentrations < 25%. However, in industrial settings significant exposure of workers to the notified polymer is not expected given the control measures in place (e.g. PPE, enclosed and automated processes, local exhaust ventilation and spray facilities) to minimise exposure.

Provided that the recommended control measures are in place to minimise exposure, the risk to workers to the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

End-use products containing the notified polymer will not be available to the public. However, members of the public may come into contact with surfaces coated with the products containing the notified polymer. Once the coatings have dried, the notified polymer will be bound within the matrix and will not be available for exposure.

Based on the assessed use patterns, the risk to the public from use of 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 be imported for reformulation in Australia. The notified polymer will be mixed with other ingredients in a mixer during reformulation. Potential release from the reformulation process may occur as

a result of residues in empty containers, from spills and leaks, and from the cleaning of equipment. Wastes from residues, leaks and spills are expected to be collected and disposed of to landfill. Empty containers, mixing vessels and transfer lines are expected to be cleaned with water and the washings are expected to be reused where possible. Therefore, a significant release of the notified polymer from the above activities to the aquatic environment is not expected.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a pigment wetting and dispersing agent for waterborne coating systems. The coatings will be used for industrial applications to primers on a variety of materials. The reformulated notified polymer will not be made available to the general public. When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that up to 20% of the coating products will form overspray and be collected as waste material. As the application of the coating is expected to be conducted at industrial sites in designated spray booths, the overspray is expected to be captured in the spray booth filters or other capture systems and expected to be disposed of to landfill. Application by brush and roller is expected to be efficient, with very little release expected from these application methods. It is expected that notified polymer in washings of the application equipment is expected to be released to the sewer. In the wastewater treatment systems, the sludge containing the notified polymer is expected to be removed and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be disposed of to landfill along with the used article at the end of its useful life. The notified polymer is expected to remain associated with the substrate to which it has been applied.

7.1.2. Environmental Fate

The majority of the notified polymer is expected to share the fate of solid paint chips or wasted articles at the end of their useful life and be disposed of to landfill. The notified polymer is expected to be strongly bound to the other components of the inert matrix of the paint and is not expected to be bioavailable nor bioaccumulative in this form. Formulated notified polymer that is disposed of directly to landfill, as wastes produced during its application or as residues in empty containers, is expected to be entrapped within a stable coating matrix and be immobile in landfill. The notified polymer disposed of to sewers will be treated at sewage treatment plants (STPs). In STPs the notified polymer is expected to adsorb to the sludge based on its high molecular weight and charged properties. Limited amounts of notified polymer remaining in the water phase will disperse and eventually degrade in the case of release to surface waters.

The notified polymer is not expected to bioaccumulate based on its high molecular weight. In landfill, soil and water, the notified polymer is expected to eventually degrade via abiotic and biotic pathways to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

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

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Charged polymers are known to be moderately toxic to algae and show low toxicity to fish and daphnids. 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. This is unlikely to apply to the charged component of the notified polymer and, therefore, it is not considered to be an over-chelation hazard to algae. Furthermore, the notified polymer is not expected to bioaccumulate based on its high molecular weight.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicity data for the notified polymer was submitted.

7.3. Environmental Risk Assessment

The Risk Quotient (RQ = PEC/PNEC) has not been quantified as the PEC and PNEC has not been calculated. The notified polymer is a charged polymer and is assumed to be of low hazard to aquatic organisms although small amounts of the notified polymer may be released to aquatic compartment during its use. The majority of the imported quantity of the notified polymer will be incorporated into an inert paint matrix and is not expected

to be mobile, bioavailable nor bioaccumulative. Therefore, on the basis of the assessed use pattern and the assumed low hazard, the notified polymer is not expected to pose an unreasonable risk to the environment.

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