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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Hydro Pliolite 050

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 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)
International Sales & Marketing Pty Ltd (ABN 36 467 259 314)
262 Highett Road
Highett VIC 3190

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, CAS number, molecular and structural formulae, molecular weight, 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 as follows: boiling point, density, vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flash point, flammability limits and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2008)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Hydro Pliolite 050 (< 60% of notified polymer)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference IR, GC and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY < 60%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None under normal conditions of use.

DEGRADATION PRODUCTS
None under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: white aqueous dispersion (product)

Property	Value	Data Source/Justification
Freezing Point	10°C	Measured
Boiling Point	100°C at 101.3 kPa (product)	Estimated
Density	1000 kg/m^3 at 25°C (product)	Estimated
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer the vapour pressure is expected to be low.
Water Solubility	Not determined	The notified polymer is water dispersible.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable groups, but the rate of hydrolysis is expected to be slow in the environmental pH range (4–9).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer may partition from water into octanol based on the presence of hydrophobic groups in the polymer. However, the notified polymer will not cross biological membranes based on its high molecular weight.
Adsorption/Desorption	Not determined	The notified polymer is expected to be immobile in soil based on its high molecular weight and presence of ionic functionality which will bind the polymer to soil sediment.
Dissociation Constant	Not determined	The notified polymer will be ionised in the environmental pH range due to the presence of acid and base groups in the polymer.
Particle Size	Average 120 nm	Measured (product data sheet). Polymer is imported in dispersion.
Flash Point	Not Determined	Imported in aqueous dispersion.
Autoignition Temperature	Not determined	Imported in aqueous dispersion.
Explosive Properties	Not determined	Expected to be stable under normal conditions of use. The notified polymer contains no functional groups that would imply explosive properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
Stable under normal conditions of use.

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
The notified polymer will be introduced into Australia as an aqueous dispersion (< 60%) in 1000 kg intermediate bulk containers (IBC).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 100	< 150	< 150	< 150

PORT OF ENTRY
Melbourne, Sydney and Brisbane

TRANSPORTATION AND PACKAGING
The notified polymer will be supplied in 1000 kg IBC, which are transported within Australia by standard trucks to formulation plants.

USE
The notified polymer is used in paint manufacture. Coatings containing up to 40% will be used by workers and do-it-yourself (DIY) applicators.

OPERATION DESCRIPTION
The notified polymer is imported as < 60% in an aqueous dispersion. Coatings containing the notified polymer will be prepared in a single batch operation *via* a closed mixing vessel. The product containing the notified polymer at < 60% is automatically pumped to the mixing vessel and mixed with other ingredients. Following quality control testing, the manufactured coatings (containing up to 40% of the notified polymer) will be transferred to packs such as 3.8 L pails for storage and sale.

Commercial painting contractors and DIY applicators will then apply the coating to interior and exterior masonry and wood profiles, primarily by brush and roller and possibly by spray. It is expected that 70% of the products will be used by professional painters and 30% by the public.

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)*
Process Operators	2	1	30
Laboratory Personnel	1	1	30
Warehouse staff	5	1	15
Transport Workers	2	1	15
Painting Contractors	25	4	200

EXPOSURE DETAILS
Transport workers and warehouse staff may come into contact with the imported solution (< 60% polymer) or manufactured coatings (40% polymer) only in the event of accidental rupture of containers.

All processes involved in the coating manufacture use tools for the transfer of ingredients, and exposure of process operators and laboratory personnel is mitigated by the use of local exhaust ventilation and personal protective equipment (PPE: chemical resistant gloves, safety glasses, steeled capped shoes and appropriate industrial clothing).

Commercial painting contractors will apply the coating mainly by brush or roller. They may wear dermal PPE to minimise the exposure to the coating.

6.1.2. Public exposure

The public may be exposed to the polymer or paint in the event of a transport accident where the packaging is breached.

Paint containing the notified polymer can be used by public in do-it-yourself (DIY) applications. The public will apply the coating mainly by brush or roller with the possible use of dermal PPE to minimise exposure.

The public may be exposed to the applied coating while wet. However, once the material is dried it is in a stable, inert form and is not expected to be bioavailable.

6.2. Human health effects assessment

No toxicity data were submitted.

Toxicokinetics, metabolism and distribution

Based on the high molecular weight (> 10,000 Da) and negligible proportion of low molecular weight species (< 1,000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited.

The mean particle size of the polymer is 120 nm, with more than 20% of particles falling within the nanoscale (1-100 nm) (observation made from a graph of size distribution by percentage). The notifier has advised Hydro Pliolite 050 (< 60% of notified polymer) is a colloidal dispersion of a polymer in water. The polymer particles, as a result of their morphology, are relatively soft and sticky, and have a minimum film formation temperature (MFFT) of approximately 7^{o}C, which means that under normal conditions they will readily form a film, without the addition of a coalescing agent, when applied to a suitable substrate such as a wall. Thus, no particulate matter is present when the product is applied as part of a coating formulation. Therefore, dermal absorption of polymer particles is not anticipated.

Eye irritation

In the MSDS for Hydro Pliolite 050, it was shown that representative latex samples were tested for eye irritation using Bovine Corneal Opacity and Permeability Assay. Latex particles adhered to the anterior cornea causing opacity. There was no permeability of the materials, no significant corneal damage and negligible to minimal effect to the lower stromal layer of the cornea observed. The study report was not available. It is expected that the notifier polymer may be slightly irritating to the eyes.

Health hazard classification

Based on the limited information available, the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

No toxicological data are available for the notified polymer. A summary provided for similar latex products showed that the notified polymer may be slightly irritating to the eyes.

Inhalation exposure may occur if the end-use products were to be applied by spray application. As information on inhalation toxicity is not available, controls to reduce exposure would be needed to ensure safe use.

Due to the control measures in place to reduce exposure, including closed mixing vessel and automated processes used for the formulation process involving the notified polymer at < 60% and the use of PPE, the overall risk of exposure to the notified polymer will be low and it is, therefore, not considered to be unacceptable to the health of workers.

6.3.2. Public health

When the do-it-yourself (DIY) applicators use the coatings containing the notified polymer (at up to 40%), they are expected to have exposure to the notified polymer less frequently than the professional painter and they may use PPE if required. The notified polymer is present as a colloidal dispersion in water. Following application to a suitable substrate such as a wall, a film will form. Therefore, dermal absorption is not anticipated. Therefore the overall risk posed by use of product containing the notified polymer by brush or roller is not considered to be unacceptable to the health of the public.

Spray application by the public of products containing the notified polymer is not expected, but could occur. As information on inhalation toxicity is not available, controls to reduce exposure would be needed to ensure safe use.

The public may also be exposed to the applied coating. However, once the material is dried it is in a stable, inert form. Therefore, exposure to the general public is very low and is not considered to be unacceptable to the health of the general public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be blended with other chemicals into finished paint products in Australia. The notified polymer is unlikely to be released to the environment in significant quantities from these processes except from accidental spills. Spilt polymer is expected to be coagulated with alcohol or alum, filtered off and collected for disposal according to State/Territory regulations. Approximately 0.1% of the annual import volume of the notified polymer may be released to sewer from the cleaning of reformulation equipment or transport containers.

RELEASE OF CHEMICAL FROM USE

The majority of the paint containing the notified polymer is expected to be used by professionals (70%) with the remainder being used by do-it-yourself (DIY) practitioners (30%). The paint will be applied to various substrates including interior and exterior masonry and wood profiles, typically with brushes and rollers. In industrial settings, application equipment will be cleaned with an appropriate cleaning solvent and washings will be held in storage tanks prior to disposal. Of the 30% of paint containing the notified polymer used by do-it-yourself (DIY) practitioners, it is estimated that 5% of the paint would be released to sewers due to washing of brushes and rollers with water. Under this scenario, 1.5% of the total import volume of notified polymer ($0.05 \times 30\%$) is assumed to be released to sewer annually.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to share the fate of the substrates to which the paint containing the polymer has been applied, and hence will be disposed to landfill. A small proportion of the notified polymer is expected to enter landfill in the form of dried paint residues in used paint containers.

7.1.2 Environmental fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight much greater than 1000 Da and no significant percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes and therefore will not bioaccumulate.

The notified polymer would be expected to be efficiently removed from waste water in waste water treatment plants through adsorption of this ionic polymer to sludge or by flocculation (Boethling and Nabholz, 1997). The notified polymer is therefore expected to be concentrated in the sludge fraction of on-site or municipal waste water treatment plants. Sludge generated during the washing process will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil and sludge due to its ionic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC was calculated assuming that 1.5% of the total import volume of polymer would be released to sewer annually, mainly from DIY use. It is further assumed that 90% of the notified polymer partitions to sludge in STPs due to its net positive charge (Boethling and Nabholz, 1997). The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	150,000	kg/year
Proportion expected to be released to sewer	1.5%	
Annual quantity of chemical released to sewer	2,250	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	6.16	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,232	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	0.15	µg/L
PEC - Ocean:	0.015	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 13.109 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.087 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 0.435 mg/kg and 0.87 mg/kg, respectively.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 42.5 mg/L	Harmful
Daphnia Toxicity	EC50 (48 h) = 42.4 mg/L	Harmful
Algal Toxicity	EC50 (96 h) = 7.2 mg/L	Toxic

The notified polymer is potentially harmful or toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for algae. The endpoint for algae was therefore selected for the calculation of the PNEC below. A conservative assessment factor of 1000 was applied since ecotoxicity endpoints were calculated using SAR equations based on groupings of broadly related polymers.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae (EC50, 96 h)	7.2	mg/L
Assessment Factor	1000	
PNEC:	7.2	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.15	7.2	0.020
Q - Ocean	0.015	7.2	0.002

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited information available, the notified polymer cannot be classified as hazardous 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 with recommended controls, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling the notified polymer (formulation workers):
  - Avoid eye contact

- Employers should ensure that the following personal protective equipment is used by workers handling the notified polymer:
  - Safety glasses

  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 *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical 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.

Public Health

- Products marketed to the public containing the notified polymer should not recommend application by spraying.

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 use in paint manufacture, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 150 tonne per year, 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Glass Transition Point 10ºC

Method	Differential scanning calorimetry
Remarks	The test was conducted from -80ºC to 80ºC at 20ºC/min with 2 heatings. Tg is determined on the second heating and is the average of 2 measurements.

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