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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in DISPERBYK-2020

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 Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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FULL PUBLIC REPORT

Polymer in DISPERBYK-2020

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Nuplex Industries (Australia) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road
Botany NSW 2019

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ 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; Methods of detection and determination; Impurities; Additives/Adjuvants, Import volume; Confidential details of use; Residual Monomers; Polymer Constituents; Identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point; Density; Vapour pressure; Hydrolysis as a function of pH; Partition coefficient; Adsorption/desorption coefficient; Dissociation constant; Particle size; Flammability limits; Autoignition temperature; Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (year unknown)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

DISPERBYK-2020 (~70%)

MOLECULAR WEIGHT

> 10000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

>96%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Tan coloured liquid

Property	Value	Data Source/Justification
Melting Point	Not determined	Will only be imported in acetate solution.
Density	1010 kg/m ³	MSDS. See discussion below
Vapour Pressure	< 10 ⁻⁸ kPa	Estimated. Expected to have a low vapour pressure based on high molecular weight.
Water Solubility	< 10 mg/L at ambient temperature	Measured
Hydrolysis as a Function of pH	Not determined	Not water soluble therefore test could not be conducted. Expected to hydrolyse at pH 5-6 based on structure.
Partition Coefficient (n-octanol/water)	log Pow > 4	Estimated based on low water solubility.
Adsorption/Desorption	Not determined	Expected to be associated with soil and sediment based on low water solubility.
Dissociation Constant	Not determined	Contains ionisable functional groups that typically dissociate at pH ~5.
Particle Size	Not determined	Will only be imported in acetate solution.
Flash Point	> 100°C at 101.3 kPa	Estimated.
Flammability	Not expected to be highly flammable	Estimated from the measured flash point
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

DISCUSSION OF PROPERTIES

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

The notified polymer has a high molecular weight, a low vapour pressure and based on its limited water solubility is expected to be lipophilic.

Density

The notified polymer will not be isolated from solution throughout its anticipated use in Australia. The specific gravity of the manufactured resin solution containing ~70% of the notified polymer is 1010 kg/m³. The specific gravity of the solvent portion of the resin solution (~30%) is 969 kg/m³.

Reactivity

The notified polymer is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as an acetate solution (up to 70%) in DISPERBYK-2020.

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

Year	1	2	3	4	5
Tonnes	10-30	10-30	10-30	10-30	10-30

PORT OF ENTRY

All major seaports throughout Australia

TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road or rail to the notifier's storage warehouse in sealed 25 kg or 200 kg drums. It will then be distributed to the manufacturing or customer sites by road or rail.

The notified polymer will be imported into Australia as a component of DISPERBYK-2020, which is classified as a Dangerous Good based on the acetate solvent present in the formulation. For this reason DISPERBYK-2020 will be securely transported as a Class 3, Packing Group III Dangerous Good.

USE

The notified polymer will be used as a component of a wetting and dispersing additive DISPERBYK-2020 (up to 70% notified polymer), used primarily in industrial inks (~30% of import volume) and industrial coatings as well as wood coatings and architectural coatings (~70% of import volume for total coating products). It is estimated that DIY users will use ~5% of the coating products (3.5% of import volume).

Final ink and coating products will contain < 5% and < 25% of the notified polymer respectively.

OPERATION DESCRIPTION

The notified polymer will be blended into printing inks or coating products at the customer site. The manufacturing process will be essentially the same for both the printing ink and coating formulations.

Coating/Ink Formulation

The notified polymer will be blended into finished coatings or inks in closed automated systems with dedicated transfer lines. The notified polymer (up to 70%) will be directly pumped from the storage drum to the blending vessel and added to the millbase. Following complete incorporation, any further additives (solvents, resins, pigments or fillers) will be added.

After formulation, the finished product will be transferred via pipes to a hopper, or similar device, where it will be emptied into metal containers that are subsequently sealed and labelled. These may be stored on-site prior to their distribution to end-use customers. All processes will occur under exhaust ventilation.

The ink (< 5%) and coating (< 25%) formulations will be sampled via taps in the blending vessel, and tested by laboratory technicians to ensure that they meet set specifications and pass quality control testing.

Manufacturing equipment will be cleaned by rinsing the vessel and transfer lines with solvents, usually mineral spirits. All washings will be stored in holding tanks on-site that will be routinely emptied by licensed waste contractors for appropriate disposal to landfill.

Printing Ink:

When used in the printing industry, the ink formulation (containing < 5% of the notified polymer) will be transferred to the labelling machine equipment and stored in an enclosed vessel. Transfer of the material will occur via automated lines that are connected to the storage drums. The labelling machine is fully automated, operates at high speeds as part of the manufacturing line, and is equipped with lamps that cure the product immediately after application.

Coatings Application:

The finished coatings (containing < 25% of the notified polymer) will be applied to substrates by spray (~75%), roller (~15%) or brush (~10%).

Mixing of the finished formulation and spray application will be conducted in spray booths located in industrial sites. The over spray will be collected within the spray booth on protective materials (e.g. kraft paper or newspaper) and any volatile materials will be captured by the filtering systems.

Application equipment, like rollers and brushes, will be cleaned with industrial solvents (such as mineral spirits), and washings will be held in storage tanks prior to disposal by licensed waste contractors.

A small proportion (~5%) of the finished coatings may be sold to the public for DIY use. The coatings in this case are expected to be applied using rollers or brushes.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Waterside	10	4	50
Storage and transport	70	4	150
Formulation			
Production of coatings	40	5	200
Production of inks	40	5	200
Lab technicians	10	2	100
Application			
Coatings	100	6	250
Printing inks	20	8	250

EXPOSURE DETAILS

Transport and Storage

Exposure to the notified polymer (up to 70% notified polymer) by waterside and storage and transport workers is unlikely, except in the case of accidental spillage or breach of packaging.

Formulation

There is potential for dermal and ocular exposure to the notified polymer during the connection or disconnection of transfer lines, during routine cleaning and maintenance of equipment, and when cleaning up spills or leaks. Exposure from other sources is likely to be low, as the manufacturing processes will be enclosed and automated. In addition, local exhaust ventilation will be used to capture any aerosols. Worker exposure will also be lowered by the proposed use of PPE, including eye protection, safety shoes, coveralls and impermeable gloves.

Dermal and ocular exposure of workers to the notified polymer (< 25%) may occur during quality control procedures. However, the extent of such exposures are likely to be low due to the small sample sizes involved, the low frequency and short duration at which the operations are performed, and the personal protective equipment worn by workers (eye protection, safety shoes, laboratory coats and impermeable gloves).

End use

Printing Ink:

Exposure to the notified polymer (< 5%) when used in printing inks may result via the dermal or ocular routes when the ink formulation is transferred to the labelling machine. However, exposure to the notified polymer should be limited by the proposed use of PPE (coveralls, safety goggles and impermeable gloves) by these workers.

Coating Application:

Dermal, ocular and inhalation exposure of workers to the notified polymer (< 25%) may occur during spray application of the coating to paper, plastic or metal substrates, and when cleaning up application equipment. Exposure during spray operations should be reduced as all spray applications will be within spray booths at industrial manufacturing facilities. In addition, workers will wear, as a minimum, eye protection, coveralls, and impermeable gloves; if necessary an air respirator will also be worn.

Dermal and ocular exposure of workers to the notified polymer may occur during brush and roller applications, particularly during manual decanting and manual application. Exposure should be reduced by the wearing of PPE, including overalls, eye protection and impermeable gloves. In addition, the finished coating is expected to be touch-dry within two hours after application, minimising the potential exposure duration.

Workers may make dermal contact with the notified polymer once the ink or coating formulation is dried to the substrate. Once dried, the coating or ink will form an inert film that will contain and immobilise the notified polymer, making it unavailable for dermal absorption.

6.1.2. Public exposure

Dermal exposure to the notified polymer (< 25%) is likely by the public when applying coating products by brush and roller through spills and splashes, and when cleaning application equipment. Accidental ocular exposure could also occur.

The general public may make dermal contact with the notified polymer once the ink or coating formulation is dried to the substrate. Once dried, the coating or ink will form an inert film that will contain and immobilise the notified polymer, making it unavailable for dermal absorption.

6.2. Human health effects assessment

No toxicity data was submitted.

Toxicokinetics, metabolism and distribution.

Given the high molecular weight, limited water solubility and expected high lipophilicity of the notified polymer, it is not expected to cross biological membranes and distribute readily to body compartments. However, a significant percentage of low molecular weight species are present.

Irritation and Sensitisation.

The notified polymer may possess irritant properties as it contains tertiary ammonium functional groups (FGEW < 1500), a structural alert for skin irritants. However, given the high molecular weight the potential for irritancy is expected to be at most moderate.

The anionic counterion to the ammonium groups is also potentially surface active and therefore may also present as a possible skin irritant. However, given the limited water solubility of the notified polymer the bioavailability of this anionic counterion is not expected.

Classification

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

No toxicity data was supplied on the notified polymer, therefore the hazards are unknown. Based on structural alerts, the notified polymer is a potential skin irritant of unknown severity. However, based on the molecular weight and limited water solubility, it is only expected to present at most moderate irritancy.

Workers most at risk will be those handling the notified polymer above 20% (i.e. formulation and coating application workers), the cut-off level for classification for skin irritants in mixtures (NOHSC, 2004). However, the notified polymer will be contained throughout its lifecycle (formulation and end-use) within a solvent that is likely to present a greater hazard to workers. As a consequence, the safety precautions that will be observed for the solvent are expected to be sufficient for the notified polymer.

Given the low potential hazard, the proposed use of PPE and the engineering controls in place, the risk to workers of the notified polymer is not considered to be unacceptable.

6.3.2. Public health

There is a moderate risk of skin and eye irritation to the public from the notified polymer when using coating products. However, given the low potential hazard of the notified polymer and that it will likely be contained within a hazardous solvent, the risk to the public to the notified polymer is not expected to increase that already presented by the solvent in the coating products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

During blending of the coating formulations, an estimated 1% of the annual introduction volume of the notified polymer may be regarded as spilt wastes. These spillages will be collected for disposal to landfill.

At most, 1% of the annual introduction volume of the notified polymer is anticipated to remain as residues in the storage containers. The storage containers are likely to be dried prior to disposal to landfill.

Manufacturing equipment will be rinsed with industrial solvents (e.g. mineral solvents). It is expected that < 1% of the annual introduction volume of the notified polymer will be lost to cleaning the manufacturing equipment. The solvent washings will be stored in holding tanks on-site for appropriate disposal by licensed waste contractors where the waste will likely undergo a flocculation process during which time the polymer will be removed and disposed to landfill.

RELEASE OF CHEMICAL FROM USE

When used as printing ink, the transfer of the ink containing the notified polymer and the labelling machine will both be automatic as part of the manufacturing line. The wastes will be disposed of to landfill. Being a solvent based product, the release into the aquatic compartment will be negligible.

When used in coatings applications, about 75% of the volume will be applied to substrates by spray and 25% by rollers and brushes. Mixing of the finished formulation and spray application will be conducted in spray booths located in industrial sites. The over spray, accounting for up to 25% of the applied coating, will be collected within the spray booth on protective materials (e.g. kraft paper or newspaper) and any volatile materials will be captured by the filtering systems. Rollers and brushes will be cleaned with industrial solvents (such as mineral spirits), and washings will be held in storage tanks prior to disposal.

The main environmental release from use may occur from DIY use of finished coating products (~3.5% of total import volume), applied using rollers or brushes. This release is expected to be 0.175% of the total volume imported and will be released during washing of equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

Articles where the coating products have been applied will ultimately end up in landfill, where the notified polymer is expected to remain immobile.

The substrates on which the ink products have been applied are likely to be recycled. During the paper recycling process, waste paper is repulped using chemical agents that enhance fibre separation, ink detachment and whiteness of the paper. These aqueous wastes are expected to go to the sewer. Negligible amounts of the notified polymer is expected to partition to the aqueous waste that is released to the sewer. The notified polymer is expected to be associated with the sludge generated during the washing process that is dried and incinerated or sent to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The majority of the notified polymer will be disposed to landfill as a result of manufacturing, storage and use. In landfill, the notified polymer is not expected to be mobile and is expected to degrade slowly to water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	0.175%	
Annual quantity of chemical released to sewer	52.500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.14	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.003	µg/L

7.2. Environmental effects assessment

No ecotoxicity data was submitted. The notified polymer is cationic. These polymers are of high concern to the aquatic environment.

7.3. Environmental risk assessment

The release into the aquatic environment is negligible based on the reported use pattern; hence the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical cannot be classified as hazardous under 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 the health of the public.

Environmental risk assessment

On the basis of the PEC and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during spray application:
 - Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC 1999)
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:

- Avoid skin and eye contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Safety goggles
 - Impermeable gloves
 - Coveralls

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.

Environment

- The following control measures should be implemented to minimise environmental exposure during formulation and use of the notified polymer:
 - All wastes and end use products should be disposed of to landfill.

Disposal

- The notified polymer should be disposed of to landfill, or licensed waste disposal.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, whilst preventing entry to drains and waterways. Do not discharge to soil or subsoil. Collect spill with adsorbent material (eg sand, vermiculite or universal binder) and place in suitable containers for 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(1) of the Act; if
 - the notified polymer has a number-average molecular weight of less than 1000 Da.
 - the notified polymer is introduced in solid form.
- or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a wetting and dispersive agent in industrial printing inks and coatings, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;

- additional information has become available to the person as to an adverse effect of the chemical 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 imported 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

Water Solubility < 10mg/ml at 20°C

Method	In-house qualitative water solubility test (non-GLP).
Remarks	Solubility was examined at the following concentrations: 100, 20, 10 and 5 mg/L. At all concentrations down to 10 mg/L, undissolved particles could be observed by visual inspection. At the concentration of 5 mg/L no undissolved particles could be observed.
Test Facility	The water solubility of the notified polymer was therefore determined to be < 10 mg/L. Data submitted by notifier (personal communication).

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.
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.