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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DREWRAD F330 Resin

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 and Water Resources.

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ashland Pacific Pty Ltd (ABN: 47 000 075 641) of Sir Thomas Mitchell Road, Chester Hill, NSW 2162

NOTIFICATION CATEGORY
Limited: Synthetic polymer with NAMW ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical names, Other names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Purity, Hazardous impurities, Non-hazardous impurities, Additives/adjuvants, Import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Freezing Point, Boiling Point, Vapour Pressure, Hydrolysis as a Function of pH, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
DREWRAD F330 Resin
Flexcure F330 Resin

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	1000-2000 Da
% of Low MW Species < 1000 Da	< 20%
% of Low MW Species < 500 Da	< 5%

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The residual monomers may be lost to the environment when the polymer or product containing it is in the liquid state.

DEGRADATION PRODUCTS
None known

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa
Viscous, clear light yellow liquid

Property	Value	Data Source/Justification
Freezing Point	< 0°C	Estimated
Boiling Point	Not possible to determine	Undergoes polymerisation on heating.
Density	1110 kg/m^3 at 25°C	MSDS
Vapour Pressure	< 0.133 kPa (temperature unspecified)	MSDS
Water Solubility	0.262-1.992 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Contains some hydrolysable functionalities but hydrolysis in the environmental pH range (4-9) is unlikely.
Partition Coefficient (n-octanol/water)	log P_{ow} = 2.181	Measured
Adsorption/Desorption	Not determined	Expected to be relatively mobile in soil due to its water solubility and moderate log P_{ow}.
Dissociation Constant	Not determined	Contains potentially cationic groups which would be expected to have pKa of 9-11.
Particle Size	Not determined	Liquid under ambient conditions.
Flash Point	93.4°C (pressure unspecified)	MSDS
Flammability	Not determined	Not expected to be highly flammable.
Autoignition Temperature	Not determined	Not expected to autoignite at ambient temperature and pressure.
Explosive Properties	Not determined	Not expected to be explosive.

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

Reactivity
The polymer is expected to be stable under normal conditions of use. When heated, the notified polymer is claimed to undergo further polymerisation.

Dangerous Goods classification
Based on the available data the notified polymer is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998):

C1 combustible liquid

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at neat concentration in 200 L phenolic-lined steel drums and 20 L phenolic-lined steel pails. The steel drums and pails will be transported to and stored at the notifier's warehouse.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 20	≤ 20	≤ 20	≤ 20

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS

Industrial coating formulators

TRANSPORTATION AND PACKAGING
The notified polymer will be transported to formulators for the formulation of UV-curable inks and coatings, which will be sold to printing and coating companies in 20 L steel pails. The concentration of notified polymer in the UV-curable inks and coatings will be in the range of 60-90%.

USE
The notified polymer will be used as an additive for the formulation of UV-curable inks and coatings. These inks and varnishes will be used to make packaging material and/or magazines.

OPERATION DESCRIPTION
Transport and storage
Following importation of the notified polymer in 20 L and 200 L steel drums, transport workers will deliver them to the notifier's warehouse for storage before distributing to UV-curable ink and coating formulators. Transport workers will also deliver the finished radiation curable inks and coatings (~60-90% notified polymer) to printing and coating companies for application on substrates such as plastic and paper.

Formulation of radiation curable inks and coatings
The liquid polymer will be formulated into UV-curable coating and ink products at the formulator's site. Formulation will involve transfer of the notified polymer and other ingredients by metered dosing to a 1000 kg stainless steel mixing vessel. This process can be operated either manually or in enclosed system. The high-speed mixers are sealed vessels fitted with a local ventilation system. Each batch will be quality checked, and adjustments will be made as required. The resultant product will be filtered prior to being dispensed under exhaust ventilation into 20 L steel pails for supply to customers. The concentration of the notified polymer in the final product will range from 60-90%. Finished products containing the notified polymer will be warehoused at the formulator's site and distributed to end user(s).

End use
Inks and coatings containing 60-90% of the notified polymer will be applied using a flexographic Anilox roll coating system to substrates (such as paper or plastic) and cured by UV-radiation. From the 20 L steel pail, the ink will be manually dispensed by the operator into the ink duct attached to the printing machine. The ink will then be transferred via the Anilox roll to the printing plate cylinder, which will in turn transfer the ink image onto the substrate being printed. The printed substrate travels approximately 60 cm to where it will be exposed to a protected UV light source that cures the ink. The printing and curing process occurs within a closed system that is supplied with exhaust ventilation.
The operator may manually wash rollers and ducts and load empty drums into washing machines for cleaning.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker/Operation	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage			
	6	2-3 hours/day	10 days/year
Ink/Coating formulation			
Ink/Coating make up	3	8 hours/day	260 days/year
QC testing	1	8 hours/day	260 days/year
Filling into pails	3	8 hours/day	260 days/year
Maintenance workers	2	8 hours/day	260 days/year
End use			
Flexographic unit operators	100-200	8 hours/day	260 days/year

Transport and storage
Exposure to the polymer will be unlikely during transportation and storage except in the case of accidental spills or leaks from the container.

Formulation of radiation curable inks and coatings
Potential ocular and dermal exposure may occur during a number of processes involving manual handling of either 100% notified polymer or products containing 60-90% notified polymer during formulation, such as during possible manual charging of the mixer, sampling and testing, connecting and disconnecting filling lines, and equipment cleaning and maintenance, workers are expected to wear personal protective equipment (PPE) during these processes. Workers' exposure is expected to be reduced where enclosed system is in place.

Inhalation exposure is expected to be low due to low vapour pressure of the notified polymer and the local exhaust ventilation system and the enclosed systems employed.

End use
There is potential for ocular and dermal exposure to inks/coatings containing 60-90% of the notified polymer during their end use in printing and coating applications, especially for workers involved in manual dispensing of inks, washing rollers and ducts and loading of empty drums into washing machines. Workers are expected to wear PPE, such as long sleeved overalls, safety glasses and PVC gloves to reduce exposure during these processes. The printing and curing process will be carried out within a closed system, so exposure is expected to be minimal or negligible during these processes. Once cured by UV onto the substrate, the notified polymer is expected to be covalently bound within the ink matrix and therefore unavailable to cause further exposure.

6.1.2. Public exposure
The notified polymer will only be used in industrial applications and will not be available to the public. The potential for public exposure during transport, storage, formulation and use of the notified polymer is expected to be negligible. The public will make repeated contact with the notified polymer in the cured form via contact with printed material, however as the notified polymer is expected to be bound in the ink matrix it will not be available to cause exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	low toxicity; LD50 >2500 mg/kg bw

The notified polymer is of moderate water solubility and logP_{ow} of between 1-4. As the notified polymer contains < 20% low molecular weight species < 1000 Da, some dermal absorption is likely.

The notified polymer was of low acute oral toxicity (LD50 > 2500 mg/kg). No other toxicological data is available.

Based on the available data, the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The notifier has classified the notified polymer as R43 (May cause sensitisation by skin contact).

The notified polymer contains a significant amount of low molecular weight species (<1000 Da) and it contains a high concern reactive functional group, which is of concern to human health for its potential to cause dermal sensitisation. In the absence of available data, the notified polymer may have skin sensitisation potential.

6.3. Human health risk characterisation
The critical health effect of the notified polymer is potential skin sensitisation.

6.3.1. Occupational health and safety

During formulation, the risk of skin sensitisation may exist, especially during the process where dermal exposure may occur, such as QC testing and possible manual transfer. Adequate workplace control measures, such as enclosed mixing progress, LEV and use of PPE renders the risk of skin sensitisation as being low.

No data is available on repeat dose toxicity. However as the notified polymer will be imported with additives that are sensitisers. It is expected that workers will use PPE and engineering controls. Therefore the risk after repeated dose is likely to be low.

During end use, the risk of skin sensitisation may be possible during manual handling of the inks/coating, containing 60-90% notified polymer, and during equipment cleaning. As the printing and curing will be carried out in enclosed systems and during manual processes workers will have skin protection, the risk of skin sensitisation is considered low.

6.3.2. Public health

Once the inks and coatings containing the notified polymer are applied to the printed material, the notified polymer will be chemically bound within the ink matrix and not bioavailable. Therefore the notified polymer is not expected to pose a risk to public health.

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 in Australia.

RELEASE OF CHEMICAL FROM USE

Release during formulation

During formulation and use of the inks and coatings it is estimated that < 900 kg per annum of notified polymer waste will be generated. This will be derived from:

Residues in import containers:	< 100 kg/annum
Release from formulation of ink:	< 400 kg/annum
Residues in formulation containers:	< 200 kg/annum
Release from use of ink:	< 200 kg/annum

It is anticipated that spills of the polymer solution and blended ink/coatings will be contained within the plant through the bunding systems in place. As the ink/coatings will be used in small batch quantities, it is expected that any spills will be relatively small in volume. Spills will be collected using absorbent material and removed by a licensed industrial waste contractor to a licensed waste landfill site.

Formulation equipment will be cleaned using solvent and licensed hazardous waste contractors will dispose waste from this process by incineration. Ink ducts and Anilox rollers will be periodically washed in washing machines using water and detergent. These liquid wastes will be collected by licensed hazardous waste contractors and treated by precipitation, centrifugation and flocculation. Solids wastes isolated from this process will be dried, encapsulated in concrete and disposed of in landfill while the remaining aqueous solution will be released to sewer.

It is expected that import drums containing residual polymer solution will be used to collect liquid waste and unused ink, and when finished with, collected by a licensed hazardous waste contractor. The liquid contents will be treated as described above and disposed of. The drums with any residual solid will be disposed of to a licensed waste landfill site. The residues in the import drums are expected to account for up to 0.5 % of the import volume (< 100 kg/year). Residues in finished product containers would account for up to 1% of the import volume (<200 kg/year). The containers are disposed of to landfill.

The remainder of the notified polymer will be incorporated into ink and applied to substrates such as paper, plastic. The majority of the notified polymer will be incorporated in printed material. Prior to leaving the printers, the printed material will be irradiated with UV light, which promotes a free radical polymerisation

process to form a high molecular weight, cross-linked compound. Therefore, once incorporated into the printed material, the notified polymer is consumed and poses little risk of release to the environment under normal conditions.

RELEASE OF CHEMICAL FROM DISPOSAL

Waste resulting from spills, formulation and residues in the empty containers are discussed above.

Regarding residues from waste paper, up to 20000 kg of the notified polymer will be used on printed paper products. Assuming that 900 kg polymer is released to the environment during formulation, residue in containers etc, this results in a worse case scenario of 900 kg per annum of the polymer being released to landfill.

In Australia, approximately 50% of printed paper is recycled. During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Despite cross linking, due to relatively high water solubility of the notified polymer, some of the cured polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

7.1.2 Environmental fate

No environmental fate data were submitted.

The notified polymer will be used as a component of UV curable inks. Once these inks have been cured the notified polymer is expected to remain within the product matrices. Hence, the majority of the notified polymer will share the fate of the articles into which it is incorporated. It is anticipated that these will be recycled, disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified polymer will remain immobile within the soil. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The following Predicted Environmental Concentration calculation assumes 10% recycling, and as a worst case scenario assumes no recovery within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	10.0%	
Annual quantity of chemical released to sewer	2,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.34	µg/L
PEC - Ocean:	0.134	µg/L

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

The notified polymer contains potentially cationic groups. Polycationics have been shown to elicit acute toxic effects in aquatic organisms by physically disrupting respiratory membranes, interfering with oxygen exchange. However, the Functional Group Equivalent Weight (FGEW) calculations for the notified polymer using the percent charge method indicates low charge density as the FGEW is above 5000 Da. Therefore, the notified polymer is not considered to be toxic towards aquatic organisms.

7.3. Environmental risk assessment

Although a risk quotient (RQ) cannot be calculated, the aquatic exposure of the notified polymer is expected to be low with a PEC of less than 1.34 µg/L. As this, worst case is expected to be well below toxicity levels to aquatic organisms. The notified polymer is therefore unlikely to show an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The notifier has classified the notified polymer as R43 (May cause sensitisation by skin contact).

and

As a comparison only, the classification of the polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Flammable liquids	4	Combustible liquid

Human health risk assessment

The notified polymer does not pose an unreasonable risk to workers and the public based on available data and under the proposed conditions of use.

Environmental risk assessment

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

REGULATORY CONTROLS

Material Safety Data Sheet

- The notifier has classified the notified polymer as R43 (May cause sensitisation by skin contact). An MSDS disclosing the identity of the polymer should be available to workers.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced and as diluted for use:
  - Automated chemical transfer apparatus during formulation and end use
  - Exhaust ventilation during formulation and end use.
  - Avoid contact with skin during equipment cleaning and maintenance

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and as diluted for use:
  - Procedures designed to minimise spillage during transfer operations
  - Avoid contact with skin

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and as diluted for use:
  - Gloves, goggles or coverall and footwear that are impervious to the notified polymer

  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.

Disposal

- The notified polymer should be disposed to landfill.

Storage

- Store in closed containers in a dry and well-ventilated area.
- The notified polymer as introduced should be stored consistent with provisions of State and Territory legislation regarding the Storage of C1 Combustible Liquids.

Emergency procedures

- Spills or accidental release of the notified polymer should be adsorbed on to inert materials.
- Shovel material into containers.
- Close containers and disposed of in accordance with regulations.

Transport and Packaging

- The notified polymer as introduced should be transported and packaged consistent with provisions of State and Territory legislation regarding the Storage of C1 Combustible Liquids.

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 polymer, 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(2) of the Act; if
  - the function or use of the polymer has changed from use as an additive for the formulation of UV-curable inks and coatings, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 20 tonnes per annum, or is likely to increase, significantly;
  - if 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 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

Vapour Pressure < 0.133 kPa (temperature unspecified)

Remarks Due to the high molecular weight of the polymer, the vapour pressure is expected to be low under ambient conditions. Furthermore, the notified polymer contains traces of volatile solvents that would preclude the reliable determination of its vapour pressure.

Water Solubility 0.262-1.992 g/L at 20ºC

Method OECD TG 120 Solution/Extraction Behaviour of Polymers in Water.
Remarks Water extraction of F330 at four different conditions and analysis on a size exclusion column indicated that the water solubility of the polymer component ranged from 0.262-1.992 g/L. At pH 2, a white precipitate formed. A slight cloudiness was observed at pH 9.
Test Facility Ashland Analytical Services and Technology (2006)

Hydrolysis as a Function of pH Not determined

Remarks The polymer contains some hydrolysable functionalities but hydrolysis in the environmental pH range (4-9) is unlikely. However, the above water solubility test showed evidence of some polymerisation decomposition at high acid or alkaline pH.

Partition Coefficient (n-octanol/water) log Pow = 2.181

Method OECD 107 Partition Coefficient (n-octanol/water): Shake Flask Method.
Remarks HPLC Method
Test Facility Ashland, Analytical Services and Technology, 2006

Flash Point 93.4ºC (pressure unspecified)

Method Seta closed cup (no further details available) (MSDS).

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/albino
Vehicle	None
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	6 F	2000	0

LD50	> 2500 mg/kg bw
Signs of Toxicity	Clinical findings included abnormal excretion (soft feces and diarrhoea, white material in the urine), and various discoloured areas due to discharges/excretions (described as clear, red, yellow and/or brown material around the mouth, forelimb(s), anogenital and/or urogenital areas).
Effects in Organs	No macroscopic findings were noted at the scheduled necropsy.
Remarks - Results	All animals survived to the scheduled necropsy. There was no remarkable body weight changes noted during the study.
CONCLUSION	The notified polymer is low toxicity via the oral route.
TEST FACILITY	WIL Research Laboratories, LLC (2006)

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