

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Uni-Rez 2221

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

Applicant(s)

Coates Brothers Australia Pty Limited (ABN 12 00 079 550)
323 Chisholm Road
Auburn NSW 2144

Notification Category

The notified polymer meets the PLC criteria.

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication:

Chemical name;
Structural formulae;
Means of identification;
Polymer constituents and;
Residual monomers and impurities.

Variation of Data Requirements (Section 24 of the Act)

No variation to the schedule of data requirements is claimed.

Previous Notification in Australia by Applicant(s)

None

Notification in Other Countries

USA
Canada

2. IDENTITY OF CHEMICAL

Marketing Name(s)

Uni-Rez 2221

3. COMPOSITION

Degree of Purity

100%

Degradation Products

None

Loss of Monomers, Other Reactants, additives, Impurities

None

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported in the form of granules

or pellets measuring 7 mm in diameter and 2 mm thickness. The pellets will be converted to ink preparations (varnish or white ink) for subsequent blending into coloured printing inks.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	100	100	100	100	100

Use

The notified polymer will be used as a component of ink preparations (varnish or white ink) for printing polyethylene film, such as packaging materials for bread bags, carrier bags and garden products. The notified polymer provides adhesion, gloss and water resistance to the dried ink film.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

Port of Entry

Sydney NSW

Identity of Manufacturer/Recipients

Coates Brothers Australia Pty Limited
323 Chisholm Road
Auburn NSW 2144

Transportation and Packaging

The notified polymer will be imported in 23 kg multi-wall paper sacks packed in container loads of 10 tonnes. The material will be transported from the dockside to the notifier's warehouse in NSW for formulation into ink preparations (varnish or white ink). The ink preparations will be packaged into 200 kg steel drums and distributed to ink manufacturers for subsequent blending into coloured printing inks. Coloured printing inks are packed in 20 and 200 kg steel containers prior to distribution to printing press.

5.2. Operation Description

The notified polymer will be imported neat in the form of round, non-friable pellets. The pellets will be manually loaded into a mixing tank along with other components, and cold stirred using a high speed stirring process to obtain ink preparations, such as clear varnish or white ink. The varnish and white ink containing 30-40% and 12.5-17.5 % notified polymer, respectively, will be filtered and packed for further formulation into coloured printing inks. During ink manufacture, the ink preparations will be diluted with solvents and packed in 20 kg and 200 steel containers for distribution to the notifier's site interstate and other printing companies. Coloured printing inks and white inks will contain 8-17% and 10-16% notified polymer, respectively.

Before printing, the ink is thinned to a low viscosity, and is distributed around the printing press by pumping into enclosed inking units. Printing inks will be applied by flexographic printing*. Printers are cleaned using solvents.

5.3. Occupational exposure

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Frequency</i>	<i>Exposure Duration</i>
Waterside workers	2-3	None expected	None expected
Transport and storage workers	4-6	10-15 days/year	2-3 hours/day
Blender operators	5-10	50-70 days/year	6-8 hours/day
Quality control staffs	2-3	50-70 days/year	6-8 hours/day

* Flexographic printing involves a rotary in-line printing method that uses flexible resilient plates with raised images and fast-drying inks to create full-colour materials.

Printer operators

50-100

230 days/year

15 hours/day

Exposure Details

Formulation

Dermal, ocular and inhalation exposure to the notified polymer is possible when manually loading the pelletised polymer into a mixing tank. The loading operation is carried out under a dust extractor and blending occurs in a closed mixing tank. Personal protective equipment (PPE) includes coveralls, dust mask, gloves and eye protection when carrying out the above activities.

Intermittent dermal exposure to the ink preparations is possible when collecting samples for quality testing. Laboratory workers will wear laboratory coats, gloves and eye protection.

Workers may also be exposed to drips and spills when drumming off ink preparations and ink products, and while connecting and disconnecting filling pipes, and during cleaning of equipment.

Ink application

Dermal, ocular and inhalation exposure may occur when thinning the ink product prior to application with the highest exposure during cleaning and maintenance of printers. The inking units are enclosed and the printing inks are distributed around the printing press through pump lines. Printing workers will wear coveralls, gloves and eye protection during printing and cleaning operations.

5.4. Release

Release of Chemical at Site

No release of the notified polymer is expected during shipping and transport. During formulation of ink preparation, <500 kg/annum of the notified polymer waste will be generated, which are mainly from washing of mixing vessel and pump lines. Less<1 tonne/annum will remain as waste residues in import container. It is expected that import drums containing residual ink preparations will be used to collect liquid waste and unused ink, which are collected by a licensed hazardous waste contractor. The liquid contents will be disposed of as described above and the drums with any residual solid will be disposed of to a licensed waste landfill site.

Release of Chemical from Use

Release from the use of printing ink is estimated at <4.5 tonnes/annum notified polymer.

Printers are cleaned periodically with a blend of ethanol, isopropanol and ethyl acetate solvent and waste from this process will be collected for solvent reclamation. The resulting solid will be disposed of to landfill. Presumably, formulation equipment will be cleaned in a similar manner with the resulting wastes disposed of as described above.

The remainder of the notified polymer will be incorporated into ink and applied to plastic substrates.

5.5. Disposal

The majority of the notified polymer will be applied to various polyethylene substrates, which at the end of their useful life, will be disposed of to landfill.

The wastes derived from the cleaning of formulation equipment, printing equipment and import empty containers will be disposed of to landfill. Given its expected low water solubility, the notified polymer will associate with the soil matrix and degrade slowly through abiotic and biotic processes.

5.6. Public exposure

The public is unlikely to be exposed to the notified polymer during transport, storage, printing ink manufacture and printing ink application, except in the event of an accidental spill.

The printing inks are used for food and general packaging; however, the packaging is not in direct contact with food. The public may make dermal contact the printed packaging material; however, the printing ink once dried and cured is firmly attached to the surface of the substrate and not available for exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Light amber solid in granule or pelletised form
Melting Point/Freezing Point	105°C
Density	808.19 kg/m ³
Vapour Pressure	1.3 x 10 ⁴ kPa
Remarks	Test report not provided.
Water Solubility	Not determined
Remarks	The notifier has provided a result and summary test report for a structurally similar polymer. The ground test substance (20 mg) was added to distilled water (1L) and stirred at 30°C for up to 3 days followed by equilibration at 20°C for 1 day. Visual assessment of the solution indicated that particulate matter was still present suggesting that the solubility of the test substance is less than 20 mg/L. On the basis of this result, the notified polymer is likely to have low water solubility.
Particle Size	Not determined
Remarks	The pelletised form of the notified polymer is round measuring 7 mm in diameter and 2 mm thick. Pellets are non-friable.
Flammability	Not flammable
Remarks	Test report not provided.
Explosive Properties	Not explosive
Remarks	Test report not provided.
Stability	Stable
Remarks	Based on similar polymers, the notified polymer is stable at temperatures between 225-250oC. At higher temperatures (in excess of 300oC), the polymer chars and produces thermal decomposition products such as carbon dioxide, water and carbon.

ADDITIONAL TESTS

Hydrolysis as a Function of pH	Not determined
Remarks	The notified polymer contains amide linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.
Partition Coefficient (n-octanol/water)	Not determined
Remarks	The partition coefficient has not been determined due to its expected low water solubility, and its likely hydrophobic nature, indicative of partitioning into the octanol phase.
Adsorption/Desorption	Not determined
Remarks	The notified polymer is expected to be relatively immobile in soil due to its

expected low water solubility.

Dissociation Constant	Not determined
Remarks	The notified polymer does not contain any groups expected to dissociate in the environmental pH range of 4-9.
Flash Point	330°C
Remarks	Test report not provided.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were submitted.

8. ENVIRONMENT

No ecotoxicological data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Solid wastes containing the notified polymer from spills and formulation will be collected and either recycled or disposed of to landfill. Empty containers will either be recycled or disposed of to landfill. Liquid wastes resulting from the cleaning equipment will be evaporated to dryness and the resulting solid residue will be disposed of to landfill.

The notified polymer is expected to have low water solubility and, as a result, will be immobile in both terrestrial and aquatic compartments. As a consequence, the notified polymer is expected to associate with the soil matrix and sediments and slowly degrade to water vapour and oxides of carbon through abiotic and biotic processes.

9.1.2. Environment – effects assessment

No ecotoxicological data were submitted for the notified polymer. Under normal usage there will be no release into the aquatic environment. The notified polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility, and is therefore not expected to bioaccumulate (Connell, 1990).

9.1.3. Environment – risk characterisation

The notified polymer will be applied in inks to various polyethylene substrates. Once dry, the notified polymer will be incorporated in a high molecular weight polymer matrix and is not expected to pose any significant risk to the environment.

9.2. Human health

9.2.1 Occupational health and safety – exposure assessment

Dermal, ocular and inhalation exposure can occur during certain formulation processes. Limited dermal exposure to drips and spills is possible when connecting and disconnecting transfer lines, overfilling of drums, and maintenance and cleaning of mixing and printing equipment. However, the notified polymer will be imported as solid, non-friable pellets, therefore, inhalation of airborne particulates should not be of concern. Exposure to significant amounts of the notified polymer is also limited because of the largely enclosed mixing and transfer operations, automated and enclosed printing ink application, and the use of engineering controls and personal protective equipment.

Once the ink has dried, the notified polymer is cured into an inert matrix, hence unavailable for exposure.

Transport and storage workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

9.2.1. Public health – exposure assessment

The notified polymer is intended only for use in industry and will not be available to the public. Members of the public may have dermal contact with the dried ink from the packaging materials. Once the ink has dried, it is reported to be strongly bound to the plastic substrate and is unlikely to be removed easily. Therefore, the potential for public exposure to the notified polymer is expected to be low.

9.2.2. Human health - effects assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The pelletised form of the polymer may cause mechanical irritation to the eyes and to the respiratory tract if inhaled. Repeated or prolonged skin contact may result in irritation.

9.2.3. Occupational health and safety – risk characterisation

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with provisions under State and Territory hazardous substances legislation must be in operation.

The control measures in place during ink formulation and end-use will ensure sufficient protection against the notified polymer. No specific reduction measures are necessary.

9.2.5. Public health – risk characterisation

The notified polymer will not be available to the public. Members of the public may make dermal contact with the dried ink on paper and plastic wrappings. However, the risk to public health will be negligible because the notified polymer is bound within a matrix and unlikely to be bioavailable.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of ink for printing packaging materials.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- The following engineering controls and work practices are required for the safe use of the notified polymer as a component of printing ink:
 - Dust extractor when manually loading pellets into mixing tanks
 - Enclosed mixing of ink preparation
 - Automated printing ink application
 - Avoid spills and splashing during transfer operations, drumming off, and cleaning and maintenance of equipment.

- The following personal protective equipment are required for the safe use of the notified polymer as a component of ink preparation, however, these should be selected on the basis of all ingredients in the formulation:
 - Gloves
 - Protective clothing which protects the body, arms and legs
 - Eye protection
 - Dust mask when manually loading pellets containing 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment 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 is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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