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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polyether Epoxy Acrylic E1CI06

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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Polyether Epoxy Acrylic E1CI06

1. APPLICANT

Coates Brothers Australia Pty Ltd of 323 Chisholm Rd Auburn NSW (ABN 12 000 079 550) has submitted a limited notification statement in support of their application for an assessment certificate for Polyether Epoxy Acrylic E1CI06.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	viscous colourless liquid
Melting Point:	< 0°C
Boiling Point:	> 180°C (decomposes)
Specific Gravity:	1.16
Vapour Pressure:	not volatile
Water Solubility:	< 1 mg/L at 25°C
Particle Size:	not relevant as the notified polymer will only be used in Australia in solution form
Partition Co-efficient (n-octanol/water):	the partition coefficient was estimated from the empirical QSAR relationship (Lyman *et al*, 1990); the polymer has low water solubility, and hence the log Pow is expected to be relatively high (>4)
Hydrolysis as a Function of pH:	the notified polymer contain groups which are susceptible to hydrolysis, but hydrolysis is not expected in the environmental pH range 4-9 due to the low water solubility

Adsorption/Desorption:	not determined; the notified polymer is expected to be immobile in soils due to its low water solubility and high log Pow
Dissociation Constant:	no dissociable groups are present
Flash Point:	> 100°C
Flammability Limits:	not flammable, combustible
Autoignition Temperature:	> 180°C
Explosive Properties:	not explosive, based on chemical structure
Reactivity/Stability:	not oxidising, stable in water, polymerises at > 180°C and under UV light

3.1 Comments on Physico-Chemical Properties

Water solubility was determined using the UV-visible method (Coates Lorilleux Research, 2000). No solubility was obtained in a preliminary test using the OECD Shake Flask Method, assessed visually, indicating the solubility was < 1 g/L. The residue remaining in the solution was dried in an oven, weighed, and the amount subtracted from the original amount of substance. The results gave a difference of 20 mg/L. It was thought that some of the dissolved material was due to the water-soluble additives contained in the notified polymer. In order to prove this, the UV spectrum of the dissolution water was measured at 254 nm and the spectrum compared to the notified polymer in acetonitrile at 1 mg/L. The results indicated the solution contained < 1 mg/L of notified polymer.

4. PURITY OF THE CHEMICAL

Degree of Purity:	~ 99 %
Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	none
Maximum Content of Residual Monomers:	none present at above the relevant cutoffs for classification of the notified polymer as a hazardous substance (NOHSC, 1999a)
Additives/Adjuvants:	confidential

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported in ready to use inks, containing < 15 % notified polymer, in 10 kg plastic containers. Alternatively, it may be imported in essentially pure form, in 200 kg stainless steel drums, for reformulation into printing inks.

The notified polymer will be a binder in UV curable inks for printing food packaging. The notifier estimates that import volumes will be less than 10 tonnes per annum during the first five years of importation.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
The notifier estimated that up to 3 each waterside workers, transport drivers, and warehouse workers may handle drums of pure notified polymer. Additional transport and storage workers may handle containers of ready to use inks as these will be transported to a number of customer sites. The notifier indicated that transport and storage workers will handle the drums or plastic containers for 2 to 3 hours per day, 10 to 15 days per year, but no exposure is expected except in the case of an accident involving damage to the packaging.

Blending and Quality Control
In the case of reformulation in Australia, the notified polymer will be blended into inks at the notifier's site. This will involve 5 – 10 blenders and 2 – 3 quality control personnel, for 5 – 6 hours per day, 50 days per year. The notified polymer will be pumped from the drums into a sealed mixing vessel, where other ink ingredients are added. The mixture will then be passed through a 3-roll mill to reduce particulates. Milling will occur under local exhaust ventilation. The finished inks will be tested for quality control purposes during blending and milling, then packed into plastic containers for shipping to printing sites.

The notifier indicated that the process will be under manual control initially, while colour blending recipes are determined. A higher degree of automation will be applied after this time. There may be occupational exposure to residual pure notified polymer when drum spears are inserted and removed on replacing drums at the blending stage. Exposure to drips and spills of the inks containing < 15 % notified polymer may occur at a number of points where the product is sampled for colour checking or other quality control testing, and during packaging. The notified polymer is not volatile, so exposure is expected to be predominantly dermal, with the possibility of ocular exposure to splashes. The notifier indicated that coveralls, neoprene or nitrile gloves and goggles will be used during blending operations.

Printing
Printing is expected to be a highly automated process. The notifier estimated that 50 – 100 workers will use the inks containing the notified polymer on a round the clock basis. Due to the automation involved, exposure is only likely during installation of new ink containers, and during cleaning of the printing equipment. These operations are expected to involve exposure only to small amounts of notified polymer, at concentrations < 15 %. Goggles, neoprene or nitrile gloves and coveralls will be worn. Following UV curing of the inks on the substrates, the notified polymer will no longer be available for exposure.

7. PUBLIC EXPOSURE

The notified polymer is intended for industrial use in commercial printing inks for professional use and will not be sold to the public. Printing inks containing the notified polymer will be cured with UV light to form an inextricably bound matrix. Therefore, public exposure to the notified polymer is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

No release of the polymer is anticipated during transport or storage from the docks to customer sites, except in the case of an accident.

During blending operations, release of the polymer to the atmosphere is not expected due to the low volatility of the notified polymer. The notifier estimates that a maximum of 100 kg of the polymer may be released to the environment each year as a result of washing of mixing vessels and pump lines following blending operations. These wastes are placed in drums and disposed of through a licensed liquid waste contractor.

During application of inks to substrates, there may be some release of the notified polymer to the environment when printing machines are washed and cleaned. The machines are cleaned with organic solvents such as alcohol and water-based detergents. The waste water is washed from the machines and captured in drums for disposal to an approved liquid waste disposal facility. The notifier estimates that a maximum of 250 kg notified polymer per annum could be released in this way depending on the nature of the printer.

A further 5 kg of notified polymer may remain as residues in empty containers. The residues will be disposed of to landfill through a licensed waste contractor.

In summary, up to 355 kg of wastes may be generated during blending and application of the notified substance. No release of the polymer is anticipated once the printing inks are UV cured and bound to the surfaces of the packaging containers, after which time the polymer will be inert.

8.2 Fate

Most of the imported volume of polymer will be used in the manufacture of ink, and will be bound up in the polymer matrix of the cured ink and deposited on packaging. The fate of the polymer will therefore follow the fate of the packaging products onto which the ink is deposited. At the end of their useful life, most printed products will be recycled, placed in landfill or incinerated. Only a small amount of waste (a maximum of 355 kg notified polymer per annum) will be generated during blending and application of ink. These wastes will be disposed of by licensed waste contractors either via incineration or in landfill.

It is expected that a large proportion of the packaging containing the notified polymer will be disposed of in domestic waste. According to Visy (2001), almost 80 % of the household waste is now recycled. Recycled containers on which the inks containing the notified polymer are used are most commonly used to make new packaging containers.

No degradation data were provided in the notification dossier. Acrylic ink coatings are resistant to thermal and photooxidation and to hydrolysis. Hence, the polymer is not expected to readily degrade in the environment. At landfill sites, the polymer will undergo slow degradation by abiotic and microbial degradation processes either directly or along with the packaging materials containing the polymer blend. Given its low water solubility, the polymer is not expected to be mobile in soils or to leach from the soil environment. The negligible vapour pressure indicates the new polymer is unlikely to partition into the atmosphere through volatilisation.

Incineration of wastes and packaging containing the notified polymer would result in the destruction of the polymer and release of oxides of carbon.

The high partition coefficient and low water solubility indicate the notified polymer will have an affinity to lipids, however, given the high molecular weight, it is not expected to cross biological membrane or bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Summary of Toxicological Investigations

Endpoint & Result	*Assessment Conclusion*
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

9.2 Acute Toxicity

9.2.1 Skin Irritation

TEST SUBSTANCE	Notified polymer
METHOD	OECD 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Observation Period	3 days
Vehicle	Test substance used as supplied
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*

	1	2	3			
Erythema/Eschar	0	0	0	1	1 hr	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results: Very slight erythema was observed in one animal at 1 hr after application; no other skin reactions were observed.

CONCLUSION: The notified polymer is non-irritating to skin.

TEST FACILITY: Safepharm Laboratories Ltd (2000a)

9.2.2 Eye Irritation

TEST SUBSTANCE: Notified polymer

METHOD: OECD 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: Three
Observation Period: 3 days
Remarks - Method: One animal was treated initially, as a pilot. No significant protocol deviations were reported.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	0.33	0.33	0	2	24 hr	0
Conjunctiva: chemosis	0	0	0	1	1 hr	0
Conjunctiva: discharge	0	0	0	2	1 hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results: Moderate conjunctival irritation was observed for all animals at 1 hr after treatment; minimal conjunctival redness persisted to 24 hr in two animals.

CONCLUSION: The notified polymer is slightly irritating to the eye.

TEST FACILITY: Safepharm Laboratories Ltd (2000b)

9.3 Overall Assessment of Toxicological Data

The notified polymer has a high molecular weight, and is not expected to be absorbed across biological membranes. Systemic toxicity due to the notified polymer is therefore not expected. Studies were undertaken to examine the skin and eye irritancy potential of the notified polymer. It was found to be non-irritating to rabbit skin, and a slight irritant to rabbit eyes. No toxicity studies for other endpoints were submitted by the notifier.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Only limited release of the notified polymer to the environment is expected as a result of incidental spills, residues in containers, and cleaning of the printing presses. All spills, residues, and residual ink washed from the printing machines are collected in drums for disposal through an approved waste disposal facility.

Most of the imported volume of polymer will be crosslinked in the polymer matrix of the coatings and will be inert. The fate of the polymer will follow the fate of the packaging materials onto which the inks are deposited. At the end of their useful life, it is expected that these products will be either recycled, sent to landfill, or incinerated.

Under normal usage, the new polymer is not expected to enter the aquatic environment. The high molecular weight of the new polymer will prevent any movement across biological membranes, hence the substance is not expected to bioaccumulate (Connell, 1990).

Given the above considerations, the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
Toxicity data for skin and eye irritation were provided by the notifier. The notified polymer is non-irritating to rabbit skin, and slightly irritating to rabbit eyes. It is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) for either end point. No toxicity data for other toxicological endpoints were submitted, and the notified polymer accordingly cannot be classified against the Approved Criteria. However, the high molecular weight and low reactivity indicate that it is not likely to have significant systemic toxicity.

Occupational Health and Safety
Exposure to the notified polymer will be predominantly during the use of pre-prepared inks, containing < 15 % notified polymer. There may at some stage be reformulation in Australia of the pure notified polymer to produce inks, and worker exposure to the pure liquid notified polymer may occur at this stage.

Use of the inks will be in enclosed automated systems, and the printed substrates will be cured by exposure to UV light, which will incorporate the notified polymer into a high molecular weight film, from which it will not be separately available for exposure. There may be exposure to the notified polymer in uncured inks during replacement of ink containers or during cleaning of the printing equipment. This is likely to involve dermal contact with small amounts of ink, with possible ocular exposure to splashes. Neoprene or nitrile gloves, industrial clothing and safety goggles should be worn during cleaning and ink container replacement.

In the case of reformulation in Australia, there may be dermal exposure to drips and spills of pure liquid notified polymer during addition to the blending tanks, and exposure to small amounts of inks is possible at a number of stages. Neoprene or nitrile gloves, industrial clothing and safety goggles should be worn during reformulation operations.

Due to the low toxicological hazard presented by the notified polymer, use under the specified conditions should not pose a significant risk to occupational health and safety.

Public Health
The notified polymer is intended for industrial use in commercial printing inks for professional use and will not be sold to the public. Since printing inks, containing the notified polymer, will be cured with UV light to form an inextricably bound matrix, the risk to the public from exposure to the notified polymer is considered low.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - gloves (neoprene or nitrile), safety goggles and industrial clothing should be worn.

  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.

13.1 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(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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REFERENCES

Coates Lorilleux Research (2000), The Determination of the Water Solubility of R4620, Reference No. tr/20000214. (unpublished report)

Connell, D.W. (1990). General Characteristics of Organic Compounds Which Exhibit Bioaccumulation. In: Bioaccumulation of Xenobiotic Compounds, CRC Press, Boca Raton, USA. p. 47-57.

Lyman W.J., Reehl W.F. and Rosenblatt D.H. (1990). Handbook of Chemical Property Estimation Methods, Environmental Behavior of Organic Compounds. American Chemical Society, Washington, DC.

National Occupational Health and Safety Commission (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

SafePharm Laboratories Ltd (2000a) Acrylic Oligomer E1CI06: Acute Dermal Irritation Test in the Rabbit, Project No. 1378/001, SafePharm Laboratories Ltd, Derby, UK. (unpublished report)

SafePharm Laboratories Ltd (2000b) Acrylic Oligomer E1CI06: Acute Eye Irritation Test in the Rabbit, Project No. 1378/002, SafePharm Laboratories Ltd, Derby, UK. (unpublished report)

Visy Recycling (2001). http://www.visy.com.au Accessed October 2001.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.