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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer E94156

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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Polymer E94156****1. APPLICANT**

Coates Brothers Australia Pty Limited of 323 Chisholm Road AUBURN NSW 2144 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer E94156.

2. IDENTITY OF THE CHEMICAL

Polymer E94156 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Other names: polyether/polyester urethane acrylate

Trade name: E94156

Number-average molecular weight: >1000

Maximum percentage of low molecular weight species
(molecular weight < 1000): <5%
(molecular weight < 500): <2%

Method of detection and determination: the notified substance can be detected using GPC and identified using infrared spectroscopy (IR)

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: viscous colourless liquid

Melting point: decomposes at >180°C (at 760 mm Hg)

Specific gravity: 1.16 g/cm³

Vapour pressure: not stated estimated as negligible

Water solubility:	not determined
Partition co-efficient (n-octanol/water):	not determined
Hydrolysis as a function of pH:	notified polymer has no hydrolysable functionalities
Adsorption/Desorption:	not determined
Dissociation constant:	notified polymer has no dissociable groups
Flash point:	>100°C
Flammability limits:	not flammable
Autoignition temperature:	not determined
Explosive properties:	not explosive
Reactivity/Stability:	not reactive

Comments on Physico-Chemical Properties

Data on vapour pressure was not supplied, however, the notifier considers that it would be negligible based on experience with similar chemicals. Water solubility is likely to be less than 1 ppm based on the notifier's experience with similar chemicals and the molecular weight and nature of the notified chemical. No information on hydrolysis was provided, however, the notified chemical has no hydrolysable functionalities; similarly the lack of dissociable groups was given as the reason for the omission of data on the dissociation constant.

Partition coefficient data is not applicable as a polymer of this molecular size (number-average molecular weight (NAMW) > 1000) with its predicted low solubility, is not expected to cross biological membranes. No measurement of adsorption/desorption was made, although upon drying the notified substance is expected to adsorb to the soil.

4. PURITY OF THE CHEMICAL

Degree of purity:	>98%
Toxic or hazardous impurities:	none known
Impurities:	<1.0%

One of the impurities present is listed as hazardous on the *List of Designated Hazardous Substances* (1) although no threshold limits for the classification of a mixture containing this chemical as hazardous are stated. It is a skin and eye irritant

in rabbits (2). It is moderately toxic to rats and induced effects in the liver and further damage to the central nervous system through repeated oral administration (2).

Another of the impurities is not listed as hazardous on the *List of Designated Hazardous Substances* (1) however it is a slight eye and skin irritant to rabbits and a possible skin sensitiser in man (2).

**Maximum content
of residual monomers:** <1.0%

Additives/Adjuvants: none stated

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a binder in printing ink formulations. The notified polymer will be imported at a rate of 1-5 tonnes/year for the first five years. The notified polymer will be imported in 25kg plastic drums. The notified polymer will be blended locally into electron beam curable printing inks.

Application of the inks to various substrates is by off-set printing at a limited number of sites. The substrates to be printed include paper/plastics such as polymer coated boards for aseptic packages. The cured notified substrate typically represents 10-20% of the total ink formulation, but will be diluted by printers, for use, to < 2%.

6. OCCUPATIONAL EXPOSURE

Exposure during transport and warehousing is unlikely and will only occur due to accidental release from storage containers. The main areas where employees will be exposed to the notified polymer will be during the blending operation and during use of the manufactured printing inks. The notified polymer is pumped into sealed mixing vessels along with other ink ingredients. The formulation is then milled to reduce particulates. Milling operations are conducted under local exhaust ventilation to reduce atmospheric contamination by volatiles released from the ink. The formulated ink, containing <25% of the notified polymer, is then packaged for distribution to printers in 10-25 kg drums. Staff involved in blending procedures will potentially be exposed to the notified polymer for periods of 5-6 hours/day for 50 days/year. During blending and milling procedures, quality control staff will sample and analyse the product and can thus be exposed to the notified polymer.

The printing inks manufactured using the notified polymer are used in offset printers and cured using electron beams. The formulations as supplied, containing <25% of the notified polymer, are diluted prior to use so that the final concentration of the notified polymer used in printing is <2%. Printers will be exposed during ink replenishment and during maintenance of the printing equipment. During maintenance cleaning agents including solvents (short to medium length chain alcohols) and water based detergents will be used, these could increase exposure through mobilisation of the notified polymer.

7. PUBLIC EXPOSURE

The notified polymer will be formulated by Coates Brothers Australia Pty Ltd into a printing ink. The printing inks will not be available to the public, and will be used in commercial printing establishments and applied to plastic/paper bottles. The final concentration of the notified polymer in the ink used on these items will be <2%. The public will be exposed to the printing inks once they have been cured on the surface of product packaging such as shampoo bottles. In such instances the polymer, which has a NAMW of >1000, will be immobilised in the matrix of the ink and should pose negligible hazard to the public.

Minor public exposure may result from disposal of unused polymer/printing ink, or accidental spillage of the notified polymer or formulated printing ink during transport, formulation and storage. However, adequate measures are described by the notifier to minimise the risk of public exposure during formulation, disposal, or in the event of accidental spillage.

8. ENVIRONMENTAL EXPOSURE

Release

Formulation of the ink products will be in a sealed mixing vessel, with ingredients pumped into it for use. Milling, to reduce particulates, is conducted under exhaust ventilation. The notifier indicated that the maximum yearly loss from blending will be ~1-2% or 100 kg. Release to the environment will be through washing of the blending tanks or spillages arising from blending. Off-specification material will be electron beam cured and disposed of at approved landfill sites. The proportion of this material is expected to be 0.1-0.2% of the printing ink formulation.

The possibility exists for spillage of the notified substance to occur upon dilution for use. Loss of notified substance will also occur during off-set printing. It has been estimated that these losses will be of the order of 0.5-5%, depending on the nature of the off-set printer. Environmental exposure during the cleaning of ink from printing machines is negligible because all washes arising from the printing machines are to be collected in drums and disposed of at approved liquid waste disposal facilities. The polymer when cured by an electron beam will bind to the paper or plastic substrate (mechanism unknown) and be widely distributed with the substrate.

Treatment and disposal of any spillages is adequately dealt with in the Material Safety Data Sheet (MSDS).

Fate

Residues from washing blending tanks, drums and printing equipment with organic solvents, such as alcohols or water-based detergents, will be collected in sealed drums. These residues will be collected for treatment at a licensed liquid waste disposal facility. The washed drums are returned to Coates for reuse. Disposal of residues will be according to government regulations.

As an electron-cured polymer the notified substance is expected to have negligible interaction with soils and in the event of a minor spill, is of low concern (3). Cured polymer will share the fate of its substrate.

Recycling is a growing industry in Australia. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance the fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. Similarly, the recycling of plastics will use a variety of physical and chemical processes.

The notifier has provided no data on the likely behaviour of the polymer during recycling processes. The hydrolysis of ether/ester linkages under alkaline conditions will be minimal due to the low solubility of the polymer. The polymer therefore is likely to survive recycling conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will arrive in landfill where it can be expected to remain intact, or be destroyed through incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

The Act does not require the provision of toxicological data for polymers of NAMW greater than 1,000. However the following studies were supplied by the notifier as part of the submission.

9.1 Acute Toxicity

Summary of the acute toxicity of Polymer E94156

Test	Species	Outcome	Reference
skin irritation	rabbit	not an irritant	4
eye irritation	rabbit	not an irritant	5

9.1.4 Skin Irritation (4)

<i>Species/strain:</i>	New Zealand White rabbit
<i>Number/sex of animals:</i>	5 female
<i>Observation period:</i>	4 hour application, 72 hours observation
<i>Method of administration:</i>	semi occluded application

<i>Time after treatment (hours)</i>	<i>Draize scores (6):</i>				
	<i>Animal #</i>				
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Erythema</i>					
1	0	0	0	0	0
72	0	0	0	0	0
<i>Oedema</i>					
1	0	0	0	0	0
72	0	0	0	0	0

ⁱ See Attachment 1 for Draize scales

Test method: in accordance with OECD Guidelines for Testing Chemicals (7)

Result: non-irritating

9.1.5 Eye Irritation (5)

Species/strain: New Zealand White rabbit

Number/sex of animals: 3 female

Observation period: 72 hours

Method of administration: 0.1 ml polymer (liquid) conjunctival sac of left eye of each rabbit

Draize scores (6) of unirrigated eyes:

Animal	Time after instillation											
	1 hour			1 day			2 days			3 days		
Cornea	<i>o^a</i>	<i>a^b</i>		<i>o^a</i>	<i>a^b</i>		<i>o^a</i>	<i>a^b</i>		<i>o^a</i>	<i>a^b</i>	
1	0 ⁱ	0		0	0		0	0		0	0	
2	0	0		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
Iris												
1		0			0			0			0	
2		0			0			0			0	
3		0			0			0			0	
Conjunctiva	<i>r^c</i>	<i>c^d</i>	<i>d^e</i>	<i>r^c</i>	<i>c^d</i>	<i>d^e</i>	<i>r^c</i>	<i>c^d</i>	<i>d^e</i>	<i>r^c</i>	<i>c^d</i>	<i>d^e</i>
1	1	1	1	0	0	0	0	0	0	0	0	0
2	1	1	1	0	0	0	0	0	0	0	0	0
3	1	0	1	0	0	0	0	0	0	0	0	0

ⁱ See Attachment 1 for Draize scales

^a Opacity ^b Area ^c Redness ^d Chemosis ^e Discharge

Test method: in accordance with OECD Guidelines for Testing Chemicals (7)

Result: slight irritant, not corrosive

9.4 Overall Assessment of Toxicological Data

Toxicological data was only provided for skin and eye irritation. In rabbits the notified polymer was not a skin irritant but was a slight eye irritant, effects were only noted one hour after application of the test chemical and no effects on the eye were apparent after 24 hours.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act.

Due to its high NAMW the notified polymer is not expected to cross biological membranes.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The polymer is unlikely to present a hazard to the environment at any stage of its use. It is expected that most of the notified substance will not be released from the processing/blending sites until it has been electron-cured. The ultimate fate of the cured polymer on substrate is disposal as land-fill. Leaching of such wastes into the soil is not expected.

Uncured polymer wastes are expected to be a maximum of 100 kg per year as a result of washing blending tanks, drums or printing equipment. Residues will be sealed in drums and treated at liquid waste disposal facilities.

The low level environmental exposure of the polymer as a result of normal use, together with its expected lack of biological activity, indicate that the overall environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Occupational exposure to the notified polymer is unlikely during transport and storage. Occupational exposure will mainly occur during blending operations when the polymer will be milled and blended to make printing ink containing <25% of the notified polymer. Exposure to this ink will also occur during printing, however the ink is further diluted with solvents resulting in a concentration of the notified polymer of <2% in the ink as used. Exposure to the notified polymer will be limited through the use of equipment and practices taken to minimise exposure to the other components of the ink such as solvents.

The notified polymer will be incorporated into industrial printing inks which will be applied to paper/plastics and cured using electron beams. Public exposure to the notified chemical will result by contact with products to which the printing inks have been applied. However, the polymer, which has a NAMW of >1000, will be immobilised in the printing ink after curing, and as such would pose a negligible public risk. The potential for minor public exposure exists during formulation, transport and disposal of the printing ink/polymer which is minimised by the recommended practices during these tasks.

The notified polymer contains low levels of a hazardous impurity and low levels of a residual monomer, however, these are at levels that are unlikely to render the notified polymer as hazardous. On the basis of the available toxicity data on skin and eye irritation in rabbits the notified polymer would not be classified as hazardous according to the criteria of Worksafe Australia (8), however it produced slight short term eye irritant effects in the rabbit so there is some potential for eye irritation if ocular exposure of employees occurs. Eye contact should be avoided.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer E94156 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to Polymer E94156 to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;
 - safety goggles should be selected and fitted in accordance with AS 1336 (9) to comply with AS/NZS 1337 (10) and eye contact with the notified polymer and products containing it avoided,
 - industrial clothing must conform to the specifications detailed in AS 2919 (11) and AS 3765.1 (12),
 - impermeable gloves or mittens conforming to AS 2161 (13) and AS 3765.1 (12),
 - all occupational footwear should conform to AS/NZS 2210 (14);
- spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- good personal hygiene should be practised to minimise the potential for ingestion;
- a copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of a Material Safety Data Sheets* (15).

This MSDS was provided by Coates Brothers Australia Pty Limited as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Coates Brothers Australia Pty Limited.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. National Occupational Health and Safety Commission, 1994. *List of designated hazardous substances* [NOHSC:10005(1994)], AGPS, Canberra, 1994
2. Toxline Silver Platter (1995). *Toxline SilverPlatter CD-ROM database, 1994-September 1995*, Silver Platter International N.V.
3. Nabholz J V, Miller P and Zeeman M (1993) "Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five", *Environmental Toxicology and Risk Assessment, ASTM STP 1179*, Wayne G. Landis, Jane S. Hughes and Michael A. Lewis, Eds. American Society for Testing and Minerals, Philadelphia, 1993, p48-49.
4. Robbins M C (1995). Project Number 3011/1 - *An Acute Skin Irritation Study in the Rabbit with Polyether/polyester Urethane Acrylate E94156*, BIBRA International, Carshalton, Surrey, UK.
5. Robbins M C (1995). Project Number 3011/2 - *An Acute Eye Irritation Study in the Rabbit with Polyether/polyester Urethane Acrylate E94156*, BIBRA International, Carshalton, Surrey, UK.
6. 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**.
7. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris, France.
8. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.
9. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.
10. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
11. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australian Publ., Sydney.
12. Standards Australia 1990, *Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals*, Standards Association of Australia Publ., Sydney.
13. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia Publ., Sydney.

14. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
15. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.

Attachment 1

The Draize Scale 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 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