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Date: May 1996

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer CN-113

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

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Polymer CN-113****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 CN-113.

2. IDENTITY OF THE CHEMICAL

Polymer CN-113 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: fatty acid modified epoxy novolak acrylate

Trade name: CN-113

Number-average molecular weight: >1000

Weight-average molecular weight: >1000

Maximum percentage of low molecular weight species
(molecular weight < 1000): <25%
(molecular weight < 500): <5%

Spectral data: IR

3. PHYSICAL AND CHEMICAL PROPERTIES

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

Melting point: not determined

Specific gravity: 1.16 g/cm³

| | |
|--|--|
| Vapour pressure: | not determined, expected to be 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 |
| Combustion products: | CO ₂ and CO |
| 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 <1ppm based on the notifier's experience with similar chemicals and the molecular weight and lack of functionality 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 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% |
| Maximum weight-percentage of residual monomers: | <5% |

One of the residual monomers is listed as hazardous on the *List of Designated Hazardous Substances* (1); the threshold limits for the classification of a mixture as hazardous are 5% as an irritant or 10% as corrosive. At the concentration in the notified polymer it is not classified as hazardous. The other residual monomers are not listed as hazardous (1,2,3).

Toxic or hazardous impurities: none >1%

One of the impurities is listed as hazardous on the *List of Designated Hazardous Substances* (1) although no threshold limits for the classification of a mixture as hazardous are stated. It has an exposure standard for atmospheric contamination of TWA 3 mg/m³ (4) and is an irritant and associated with contact dermatitis in humans (2).

Another impurity is listed as hazardous on the *List of Designated Hazardous Substances* (1) although no threshold limits for the classification of a mixture as hazardous are stated. It has an exposure standard for atmospheric contamination of TWA 5 mg/m³ (4) and is a severe eye and skin irritant (2).

Non-hazardous impurities: none >1%

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 UV cured 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 10-20% 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 by UV light. The formulations as supplied, containing 10-20% 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, to act as a binding agent, at a concentration of 10-20%. The formulation will be further diluted by printers prior to application so that the final concentration of the notified polymer in the ink will be approximately 2%. The printing inks will be cured by UV light, and will be used on paper/plastic bottles eg shampoo bottles. The notifier has stated, that once cured, the notified polymer will be inextricably bound within the matrix of the printing ink.

The printing inks, containing the notified polymer, will not be available to the public, and will be used in commercial printing establishments. The public will be exposed to the printing inks once they have been cured on the surface of product packaging eg 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 UV-cured and disposed of at approved landfill sites. The proportion of this material is expected to be 0.1-0.5% 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. Environmental exposure of the notified substance at the printing stage may also occur as a result of ink-fly^a release, but this exposure has been measured as negligible. The polymer when UV-cured 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 UV-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 (5). 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 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.

^a Ink-fly consists of fine droplets of ink projected into the air by the parting of either the press rollers and/or the blanket and the paper.

9. EVALUATION OF TOXICOLOGICAL DATA

The Act does not require the provision of toxicological data for polymers of NAMW greater than 1,000. However, a study on skin irritation in rabbits was supplied by the notifier as part of the submission.

9.1 Acute Toxicity

9.1.4 Skin Irritation (6)

Species/strain: New Zealand White rabbit

Number/sex of animals: 6 female

Observation period: 24 hour application, 72 hours observation

Method of administration: semi occluded application to one intact and one abraded site on each rabbit

Draize scores (7): 0.8

| <i>Time after treatment (hours)</i> | <i>Animal #</i> | | | | | |
|-------------------------------------|-----------------|----------|----------|----------|----------|----------|
| | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> | <i>6</i> |
| Erythema | | | | | | |
| 24 (intact) | ⁱ 1 | 1 | 1 | 1 | 1 | 1 |
| 24 (abraded) | 1 | 1 | 1 | 1 | 1 | 0 |
| 72 (intact) | 0 | 0 | 0 | 0 | 0 | 0 |
| 72 (abraded) | 0 | 0 | 0 | 0 | 0 | 0 |
| Oedema | | | | | | |
| 24 (intact) | 1 | 0 | 1 | 0 | 1 | 0 |
| 24 (abraded) | 1 | 0 | 1 | 1 | 1 | 1 |
| 72 (intact) | 0 | 0 | 0 | 0 | 0 | 0 |
| 72 (abraded) | 0 | 0 | 0 | 0 | 0 | 0 |

ⁱ See Attachment 1 for Draize scales

Test method: based on Consumer Product Safety Commission of the USA (8)

Result: mild irritant

9.4 Overall Assessment of Toxicological Data

Toxicological data was only provided for skin irritation. In rabbits the notified polymer was a mild skin irritant, effects were noted on both abraded and intact skin; no effects on the skin 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. The 20.6% component of the post-reacted polymer that has a NAMW < 1000 has been identified as AICS-listed.

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 UV-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 10-20% 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.

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 hazardous impurities and low levels of a hazardous 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 irritation in rabbits the notified polymer would not be classified as hazardous according to the criteria of Worksafe Australia (9). However it produced mild short

term skin irritant effects in the rabbit so there is potential for skin irritation via exposure to employees. Eye irritation is also likely based on the results of the skin study, therefore skin and eye contact should be avoided. Two impurities in the chemical have atmospheric exposure standards.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer CN-113 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to Polymer CN-113 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;

The appropriate respiratory device should be selected and used in accordance with Australian Standard/ New Zealand Standard (AS/ NZS) 1715 (10) and should conform to AS/NZS 1716 (11).

safety goggles should be selected and fitted in accordance with AS 1336 (12) to comply with AS/NZS 1337 (13) and skin and eye contact with the notified polymer and products containing it avoided,

industrial clothing must conform to the specifications detailed in AS 2919 (14) and AS 3765.1 (15),

impermeable gloves or mittens conforming to AS 2161 (16) and AS 3765.1 (17),

all occupational footwear should conform to AS/NZS 2210 (18);

- 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* (18).

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. Sax N I, Lewis R J (1984). *Dangerous Properties of Industrial Materials* (7th Edition). Van Nostrand Reinhold.
4. National Occupational Health and Safety Commission 1995, *Exposure Standards for Atmospheric Contaminants in the Occupational Environment* [NOHSC:3008 (1995), 1003(1995)], Australian Government Publishing Service Publ., Canberra.
5. 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.
6. Liggett M P, Mcrae L A (1990). Project Number 90769D/CVP 8/SE - *Irritant Effects on Rabbit Skin of E89420*, Huntingdon Research Centre, Farnborough, Kent, UK.
7. 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.
8. Consumer Product Safety Commission of the USA in the Code of Federal Regulations, Title 16, Section 1500.41

9. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.
10. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1715-1994, Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
11. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 1716-1994, Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.
12. Standards Australia 1994, *Australian Standard 1336-1994, Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.
13. 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.
14. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing*, Standards Association of Australian Publ., Sydney.
15. 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.
16. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves)*, Standards Association of Australia Publ., Sydney.
17. 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.
18. 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 |