

October 2001

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**Speedcure PBZ**

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.

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, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9 AM and 5 PM Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

*Street Address:* 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA  
*Postal Address:* GPO Box 58, SYDNEY NSW 2001, AUSTRALIA  
*Telephone:* (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director  
Chemicals Notification and Assessment

## **TABLE OF CONTENTS**

|   |   |
|---|---|
| FULL PUBLIC REPORT.....   | 3 |
| 1. APPLICANT .....  | 3 |
| 2. IDENTITY OF THE CHEMICAL.....  | 3 |
| 3. PHYSICAL AND CHEMICAL PROPERTIES .....                                   | 3 |
| 4. PURITY OF THE CHEMICAL.....  | 4 |
| 5. USE, VOLUME AND FORMULATION .....  | 5 |
| 6. OCCUPATIONAL EXPOSURE .....  | 5 |
| 7. PUBLIC EXPOSURE .....  | 5 |
| 8. ENVIRONMENTAL EXPOSURE.....  | 6 |
| 9. EVALUATION OF TOXICOLOGICAL DATA .....                                   | 6 |
| 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS .....                               | 7 |
| 11. ASSESSMENT OF ENVIRONMENTAL HAZARD .....                                | 7 |
| 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY<br>EFFECTS..... | 7 |
| 13. RECOMMENDATIONS .....   | 8 |
| 14. MATERIAL SAFETY DATA SHEET .....  | 9 |
| 15. REFERENCES .....  | 9 |

**FULL PUBLIC REPORT****Speedcure PBZ****1. APPLICANT**

Coates Brothers Australia Pty Ltd (ACN 000 079 550) of 323 Chisholm Road, AUBURN NSW 2144 has submitted a limited notification statement in support of their application for an assessment certificate for Speedcure PBZ.

**2. IDENTITY OF THE CHEMICAL**

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

**Marketing Name:** Speedcure PBZ

**Method of Detection and Determination:** Infrared (IR) spectroscopy.

**Spectral Data:** An IR spectrum was provided.

**3. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance at 20°C & 101.3 kPa:** White powder.

**Melting Point:** 97-100°C

**Boiling Point:** Approximately 420°C at atmospheric pressure.

**Density:** 1250 kg/m<sup>3</sup>

**Vapour Pressure:** 0.236 kPa at 25°C

**Water Solubility:** < 10 mg/L (experimental)  
4.8 mg/L (estimated)

**Partition Co-efficient (n-octanol/water):** log P<sub>ow</sub> = 4.6

**Hydrolysis as a Function of pH:** Not determined – see comments

|                                  |   |
|----------------------------------|---|
| <b>Adsorption/Desorption:</b>    | Not determined – see comments   |
| <b>Dissociation Constant:</b>    | Not determined – see comments   |
| <b>Particle Size:</b>            | 106 – 800 micron: 40.8%<br>38 – 106 micron: 31.4%<br>1 – 38 micron: 27.8% |
| <b>Flash Point:</b>              | > 420°C   |
| <b>Flammability Limits:</b>      | Not flammable.  |
| <b>Autoignition Temperature:</b> | > 420°C   |
| <b>Explosive Properties:</b>     | Not explosive   |
| <b>Reactivity/Stability:</b>     | Not reactive  |

### 3.1 Comments on Physico-Chemical Properties

The notifier conducted preliminary water solubility studies based on OECD TG 105 that suggest the water solubility of the notified chemical is likely to be less than 10 mg/L (Coates Lorilleux, 2001). This is consistent with the notified chemical's predominantly hydrocarbon structure. A value for the water solubility estimated from the partition coefficient using  $\log 1/S = 1.214 \log Kow - 0.85$  was found to be 4.8 mg/L (Lyman, 1990).

The notified chemical does not contain any hydrolysable groups.

The partition coefficient of the notified chemical was determined using HPLC according to Method A8 of Directive 92/69/EC (Chilworth Technology, 2000). The log partition coefficient of the notified chemical is 4.6, which indicates it is very hydrophobic.

No adsorption/desorption tests were conducted for this notification. The notified chemical is expected to be relatively immobile in soil due to its low water solubility and high log P.

Although no tests were conducted, the notified chemical will not dissociate as it does not contain any functional groups able to undergo dissociation.

## 4. PURITY OF THE CHEMICAL

|  |  |
|--|--|
| <b>Degree of Purity:</b>                             | Approximately 100%                                 |
| <b>Hazardous Impurities:</b>                         | None.  |
| <b>Non-hazardous Impurities (&gt; 1% by weight):</b> | None.  |
| <b>Additives/Adjuvants:</b>                          | 4-methoxyphenol (CAS No. 150-76-5) is present as a |

stabiliser at a maximum concentration of 0.1%. This chemical has a NOHSC exposure standard of 5 mg/m<sup>3</sup> (TWA) (NOHSC, 1995)

## **5. USE, VOLUME AND FORMULATION**

The notified substance will be used as a component in printing ink formulations. It is to be imported at a level of less than 1 tonne per year for the first five years. The ink formulation is a mixture of pigment, acrylate polymer, acrylates, photoinitiator, wax and stabiliser. The notified chemical is present at a concentration of less than 5% and is imported in small robust plastic containers of 3 – 20 kg capacity. Blended inks are packaged in 25 kg containers.

## **6. OCCUPATIONAL EXPOSURE**

Printing inks containing the notified chemical will be transported to the notifier's premises and up to 25 customer sites following colour blending (if necessary) in containers of up to 25 kg capacity. Transport and storage workers (6 – 9) working 2 – 3 hours per day, 10 – 15 days per year should only be exposed in the event of accidental rupture of the containers. As formulated printing inks are typically viscous liquids they are unlikely to be widely dispersed in the event of an accident and exposure can be avoided if the procedures outlined in the attached Material Safety Data Sheet for a typical printing ink are followed.

### *Ink manufacture*

When a non-standard ink colour is required, ink blending is undertaken. This involves small scale (50 – 100 g) colour matching followed by full scale blending and sampling for quality control during which the inks are tested for colour in the same way as is done for the small scale colour matching. Workers (5 – 10) will spend 2 – 3 hours per day, 50 days per year in these processes which involve pumping the ink to a closed blending vessel and dispensing via gravity feed into the ink containers. Maximum losses are estimated at 2% and a maximum of 20% of the imported inks would be used for blending. Blending and quality control (2 – 3) personnel are required to wear coveralls, nitrile gloves and eye goggles to prevent the mainly dermal exposure expected. Similarly exposure is possible during washing of blending vessels and lines with solvent and/or detergent. Initially the blending will be carried out manually to establish the recipe after which blending will be automated.

### *Printing*

Printers (50 – 100) working up to 15 hours per day, 230 days per year add ink to the printing machines via pump feed. The printing machines are enclosed and the ink is typically dosed automatically. Cleaning of the machines with solvent and/or detergent is infrequent as the ink residues can be left in the machines between print runs. The washings are captured in drums for disposal to an approved liquid waste disposal facility. It is industry practice to wear coveralls, eye goggles and gloves during cleaning.

## **7. PUBLIC EXPOSURE**

The public is unlikely to be exposed to inks containing the notified chemical during transport

and storage, ink blending, ink disposal and printing as these are all industrial processes. The inks are principally used on food packaging (on surfaces not in contact with the food) and once cured will be bound to the printed surface. The public may be exposed to the cured ink but the notified chemical will not be bioavailable.

## **8. ENVIRONMENTAL EXPOSURE**

### **8.1 Release**

The notifier estimates that up to 0.02% of the yearly import volume of the notified chemical will be lost during reformulation and the cleaning of equipment. The residues remaining in the empty import containers will be disposed of in landfill by licensed waste disposal contractors while liquid wastes from the cleaning of equipment will be incinerated. Any ink from spills and any off-specification material will be cured and disposed of to a licensed waste landfill site. It is estimated that up to 2 kg of the notified chemical will be lost in this manner. There will be no release to the sewer.

Ink from the printing process will be cured and passed on to licensed waste disposal contractors for disposal in landfill while liquid wastes from the cleaning of printing machines will be incinerated. The empty plastic ink containers and any residual ink they contain will also be disposed of in landfill. The notifier estimates that up to 27 kg per annum of the notified chemical will be disposed of from the printing process in each of the first five years.

The ultimate fate of the printed material will be disposal in landfill. However, after the ink has been exposed to UV light, the notified chemical is consumed in the polymerisation process.

### **8.2 Fate**

The majority of the notified chemical will be incorporated in printed food packaging material. However, prior to leaving the printers, the printed material is irradiated with UV light and the notified chemical becomes part of a high molecular weight, crosslinked compound. Therefore, once incorporated into the printed material, the notified chemical is consumed and poses little risk to the environment.

The wastes containing the notified chemical generated during the reformulation process will be cured and disposed of in landfill. The notified chemical has a log partition coefficient of 4.6 and a relatively low water solubility. Therefore in landfill, any uncured notified chemical will associate with the soil matrix and will not leach into the aquatic environment.

Liquid wastes containing the notified chemical will be incinerated by licensed waste disposal contractors and are expected to produce water vapour and oxides of carbon.

The notified chemical has the potential to bioaccumulate (Connell, 1990), but this is not expected to occur due to its low water solubility.

## **9. EVALUATION OF TOXICOLOGICAL DATA**

No toxicological data were provided.

## **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

No ecotoxicological data were provided.

## **11. ASSESSMENT OF ENVIRONMENTAL HAZARD**

The majority of the notified chemical will be incorporated in printed food packaging material. Prior to leaving the printers, the printed material is irradiated with UV light which promotes a free radical polymerisation process to form a high molecular weight, crosslinked compound. Therefore, once incorporated into the printed material, the notified chemical is consumed and poses little risk to the environment.

The wastes containing the notified chemical generated during the reformulation process will be cured and disposed of in landfill. The notified chemical has a log partition coefficient of 4.6 and a relatively low water solubility. Therefore in landfill, any uncured notified chemical will associate with the soil matrix and not leach into the aquatic environment.

Liquid wastes containing the notified polymer will be incinerated by licensed waste disposal contractors and are expected to produce water vapour and oxides of carbon.

The low environmental exposure of the notified polymer as a result of the proposed use indicates the overall environmental hazard should be low.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

### **Hazard Assessment**

The Material Safety Data Sheet for Speedcure PBZ suggests that the notified chemical is of very low acute oral toxicity in rats (LD50 = 4700 mg/kg) is not a skin irritant and is not mutagenic in bacteria. Toxicity reports were not available to confirm these observations.

The MSDS for a typical printing ink lists the health effects as harmful by ingestion, irritant to skin, severely irritating to eyes and the vapour as irritating to the nose, throat and respiratory tract. The MSDS states that the ink is hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) although no toxicological data are listed.

### **Occupational Health and Safety**

Transport and storage of the sturdy plastic containers (capacity up to 20 kg) containing ink formulations with the notified chemical at a concentration of less than 5% should result in minimal worker exposure and consequent health effects even in the event of accidental container rupture.

Workers may be involved in some blending of colours (about 20% of the imported volume)

in which small volumes are tested for colour matching prior to pumping inks to enclosed blending vessels. Small samples are taken for colour determination and adjustment if necessary. Initially inks will be blended by hand until recipes are established. The final batch is then pumped into vessels of 25 kg capacity. The blend tanks, pumps and lines are flushed with short chain alcohols or water and the washings collected in drums for disposal. The notifier suggests that losses during these processes are small. This, together with the low concentration of notified chemical in the imported inks suggests that the risk to workers of adverse health effects from exposure to the notified chemical should be minimal. There may be some risk of skin, eye or respiratory irritation from exposure of workers to other components of the inks but this is controlled by the use of coveralls, gloves and eye goggles. Employers are responsible for maintaining the atmospheric concentration of ink components below the NOHSC exposure standards.

After transport to printers the ink is pumped to an enclosed printing press. The ink is cleaned from the press infrequently with short chain alcohols or detergent and the washings placed in drums for disposal. Printers wear eye goggles, coveralls and gloves which, together with the low concentration of the notified chemical in the inks should result in minimal exposure. Therefore, the risk to printers of adverse health effects from exposure to the notified chemical is low. Again, there may be some risk of skin, eye or respiratory irritation from exposure of workers to other components of the inks but this is controlled by the use of coveralls, gloves and eye goggles.

## **Public Health**

The risk to the public of adverse health effects from exposure to the notified chemical is minimal. There is virtually no exposure expected during transport, storage, use or disposal of the inks containing the notified chemical and it is not bioavailable in the cured ink on the packaging to which the public is exposed.

## **13. RECOMMENDATIONS**

### *Control Measures*

#### Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical 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. Exposure standards for the adjuvant, 4-methoxyphenol and the pigment carbon black (TWA 3 mg/m<sup>3</sup>) should be adhered to.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the printing inks containing the notified chemical:
  - coveralls, nitrile gloves and eye goggles



Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

### **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 representative inks containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (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**

Connell D W (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D W, (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.

Chilworth Technology (2000) Report number GLP/7870/25600: Physico/Chemical Testing on a Sample of Speedcure PBZ, Southampton, UK, (unpublished report submitted by Coates Lorilleux).

Coates Lorilleux Pty Ltd (2001) Report number 20010269: Coates Lorilleux Research Analytical Science Report (water solubility), Kent, UK, (unpublished report submitted by Coates Lorilleux).

Lyman W J, Reehl W F and Rosenblatt D H (1990) *Handbook of Chemical Property Estimation Methods*. American Chemical Society reprint.

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.

National Occupational Health and Safety Commission (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)], Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards, Australian Government Publishing Service, Canberra.

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

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

## Attachment 1

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

| <b><i>Erythema Formation</i></b>          | <b><i>Rating</i></b> | <b><i>Oedema Formation</i></b>  | <b><i>Rating</i></b> |
|---|----------------------|---|----------------------|
| 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***

| <b><i>Opacity</i></b>  | <b><i>Rating</i></b> | <b><i>Area of Cornea involved</i></b> | <b><i>Rating</i></b> |
|--|----------------------|---------------------------------------|----------------------|
| 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***

| <b><i>Redness</i></b>   | <b><i>Rating</i></b> | <b><i>Chemosis</i></b>                              | <b><i>Rating</i></b> | <b><i>Discharge</i></b>  | <b><i>Rating</i></b> |
|---|----------------------|---|----------------------|--|----------------------|
| 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***

| <b><i>Values</i></b>  | <b><i>Rating</i></b> |
|---|----------------------|
| 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.