

File No: NA/146

Date: July 18, 1994

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**COUPLING ADDITIVE U8006**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* 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 Human Services and Health.

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****COUPLING ADDITIVE U8006****1. APPLICANT**

Hoechst Australia Limited, 606 St Kilda Road, Melbourne Victoria 3004

**2. IDENTITY OF THE CHEMICAL**

Coupling Additive U8006 can be classified as hazardous according to Worksafe Australia's Hazardous Substances Regulations due to its irreversible eye irritation effects. However, for commercial reasons, the identity, impurities, specific use, import volume, identity of sites, process description, methods of detection and determination, and identity of monomer ingredients have been granted exemption from the Full Public report. The following conditions shall govern its use:

- the single site referred to in the notification is to remain the only site of use of the technical product, and only the pigments containing Coupling Additive U8006 at  $\leq$  5% shall be distributed and used at other sites,
- the full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- the full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. if they request it,
- the Director of NICNAS will release the full chemical name etc. in the case of a request from a medical practitioner; and
- confidentiality will expire after a 3 year period.

**Chemical name:** Amine salt of an alkoxyated resin.

**Trade names:** U8006  
Coupling Additive U8006  
Hoe CG 0358 OD ZD00 0001  
HOE S 4182

**Method of detection and determination:**

Analytical methods: Coupling Additive U8006 can be identified spectroscopically (UV/VIS, IR and NMR spectra) and with capillary electrophoresis, but quantitative methods are unavailable.

### 3. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance at 20°C and 101.3 kPa:</b>	Waxy and yellow.
<b>Odour:</b>	Slightly amine.
<b>Melting Point/Boiling Point:</b>	No melting point but softening occurs at 51-53°C.
<b>Density:</b>	1072 kg/m <sup>3</sup> at 55°C.
<b>Vapour Pressure:</b>	< 0.1 kPa at 100°C.
<b>Water Solubility:</b>	> 500 g/L at 20°C.
<b>Fat Solubility:</b>	Not provided.
<b>Partition Co-efficient (n-octanol/water) log P<sub>O/W</sub>:</b>	Not measured. As the resin is a water soluble salt, partition coefficient is expected to be low. Its surface active properties would preclude measurement.
<b>Hydrolysis as a function of pH:</b>	Not measured. The resin contains ester linkages and is said to be possibly hydrolysable under strongly acidic or caustic conditions. Hydrolysis would not be expected to proceed at significant rates under normal environmental conditions.
<b>Adsorption/Desorption:</b>	Test not performed. The notified substance is required to sorb strongly to azo pigments and undergoes strong sorption to solid surfaces in general.
<b>Dissociation Constant:</b>	Not measured. The resin has a pH of about 9 at a concentration of 10 g/L.
<b>Flash Point:</b>	Approximately 90°C.

<b>Flammability Limits:</b>	The substance decomposes at temperatures above 370°C as determined by differential thermal analysis.
<b>Combustion Products:</b>	Nitrous gases (NO <sub>x</sub> )
<b>Pyrolysis Products:</b>	Traces of NH <sub>3</sub>
<b>Decomposition Temperature:</b>	> 370°C
<b>Decomposition Products:</b>	Not provided.
<b>Autoignition Temperature:</b>	Not provided.
<b>Explosive Properties:</b>	Not explosive and is insensitive to shock, heat and friction.
<b>Reactivity/Stability:</b>	No risk of dangerous reactions.
<b>Viscosity:</b>	2933 mPa.s at 90°C.
<b>pH Value (10 g/L in water)</b>	8.8 - 9.2 at 20°C

#### **4. PURITY OF THE CHEMICAL**

**Degree of purity:** ~100%

**Additives/Adjuvants:** None

#### **5. INDUSTRIAL USE**

Coupling Additive U8006 is to be used in the manufacture of yellow azo pigments which will be used for printing inks. The role of the coupling additive is to improve the performance of pigments in printing inks. The notified chemical is a surface active substance which totally coats the surface of the azo pigments. It is linked to the pigment particles by adsorption, not chemical bonding.

Coupling Additive U8006 is to be imported as the technical product and also as a formulated pigment containing the coupling agent.

Coupling Additive U8006 will be imported from Germany where it is a new substance and has been neither used widely nor produced over a long time. To date no work related health effects have been reported in Germany.

## **6. OCCUPATIONAL EXPOSURE**

Technical Coupling Additive U8006 will arrive in Australia packaged in 146 kg plastic drums from which quantities will be weighed out as necessary and the containers reclosed. The formulated pigment product will also arrive in Australia or else be packaged by Hoechst in 10 - 20 kg multi layer paper sacks inside fibreboard cartons. These packages will usually be wholly used during each batch of ink production.

The notified polymer in its technical form will be used only by Hoechst where it will be reformulated into pigment products. The pigment will then be redistributed to 3-5 other companies, who will proceed with ink production.

It is anticipated that the following numbers and categories of workers will be exposed to the polymer and pigments containing it:

warehouse personnel	12
production personnel	30
packaging operators	10
dispatch personnel	10
engineering fitters	10

One Hoechst worker will be exposed to the polymer during the process of transferring Coupling Additive U8006 from the 146 kg drums to the container used for pigment manufacture. One person is expected to produce the pigment. It is estimated that each of these workers will be handling Coupling Additive U8006 on 65 occasions per year for 15 minutes on each occasion. Two Hoechst warehouse workers will receive consignments of the packaged polymer on several occasions each year and therefore be indirectly exposed to the polymer.

The remainder of the personnel described above will be exposed only to the powdered pigments containing the notified polymer. Of these, the production personnel are exposed directly to the pigments and therefore require protection. Production personnel will generally be involved in transfer processes and it is estimated by Hoechst that they will be exposed to Coupling Additive U8006 for between 300 and 400 hours per year. The remainder will be exposed only to the packaged product from which protection is unnecessary. Automatic procedures are normally used for ink packaging, thus preventing the packaging operators from exposure. Dry cleaning methods that generate dust will not be used and the plant is cleaned at the end of each shift. Engineering fitters may be exposed to Coupling Additive U8006 during maintenance (30 hours per year) unless the equipment is thoroughly cleaned beforehand.

## **7. PUBLIC EXPOSURE**

The packaging will prevent public exposure to the polymer during importation, transportation and storage. The public is also unlikely to be exposed to the polymer during pigment formulation. Small amounts of the pigment (about 2%) will be lost to the plant effluent system, mainly during cleaning, and

will be completely removed from effluent waters and disposed to an appropriate site.

The public may come into contact with the chemical in printed publications which have used inks incorporating the polymer.

## **8. ENVIRONMENTAL EXPOSURE**

### **. Release**

Local reformulation of the notified substance will only be carried out by Hoechst Australia Limited at its Organic Pigments Plant in Altona, Vic. Pigment and coupler are reacted together in the third stage of a seven stage process. Pigments are dispersed in water and reacted with an aqueous slurry of the coupling agent. After reaction, treated pigments are separated by filtration, extruded, dried, and packaged for sale as a dry powder.

Under normal operating conditions, approximately 2% of the pigment is lost to effluent treatment, mainly through equipment cleaning. Pigment residues are completely removed from aqueous waste streams by clarification and filtration, and disposed to landfill. The notifier estimates that a total of 33 - 67 kg of the coupling additive will be so recovered for disposal per annum. Clarified effluent passes to sewer. It is not possible to detect unreacted residues of the coupling agent in production effluent using capillary electrophoresis (limit of detection 10 mg/L).

Treated pigments will be formulated into inks by four companies, two each in suburban Melbourne and suburban Sydney. Ink formulae typically contain mineral oil, ink varnish and small amounts of wax. Dedicated production lines eliminate the need for routine cleaning, but where this is required, solvents would normally be used and recovered for the next batch of ink. Significant waste generation from ink production is therefore not expected. The only wastes expected from printing operations are packaging materials, which will be disposed of to landfill.

Environmental exposure to the notified coupler will occur when paper printed with the treated pigments is recycled or disposed of. In the former case, the coupler/pigment/ varnish complex would be expected to detach from the fibres and become part of the sludge. Disposal of waste paper or sludge to landfill would immobilise the pigment residues, while incineration would destroy them.

### **. Fate**

The bulk of the coupler will become fixed to pigment and in this state is not expected to impact on the environment. The notifier has indicated that fixation occurs through strong sorption and not through formation of chemical bonds.

Minor pigment residues will either be disposed of to landfill, where they would remain immobile, or be destroyed by

incineration. Resinated pigment residues in waste paper will be disposed of in similar fashion. The notified coupler is not expected to enter aquatic systems in significant amounts as its maximum concentration in production effluent is below 10 mg/L. Sorption, biodegradation and dilution during sewage treatment would reduce such concentrations to negligible levels.

Starting from an initial dissolved organic carbon (DOC) concentration of 190 mg/L, 40% loss of DOC was observed in a 28 d modified Zahn - Wellens test (OECD Test Guideline No 302B) (1) indicating that the substance may be regarded as inherently biodegradable (2). Non-biological effects are excluded from the above result, but were found to be significant (23% sorption to activated sludge after 3 h).

Neither accumulation nor bioaccumulation would be expected in view of the high water solubility and inherent biodegradability.

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

Toxicological data are not required to be submitted for this polymer as it has a number average molecular weight > 1000. However this information was provided by Hoechst and was therefore assessed.

### **9.1 Acute Toxicity**

Table 1 Summary of the acute toxicity of Coupling Additive U8006

<b>Test</b>	<b>Species</b>	<b>Outcome</b>	<b>Reference</b>
oral	female rat	LD50: 1250mg/kg	3
dermal irritation	rabbit	moderate irritant	4
eye irritation	rabbit	severe irritant	5

#### **9.1.1 Oral Toxicity (3)**

This study was conducted in accordance with *OECD guideline No: 401* (6).

U8006 dissolved in water was administered by gavage to 20 Wistar rats. Three groups of 5 females were treated with 1600, 2000 or 2500 mg/kg body weight, and 5 males were treated with 2000 mg/kg. Animals were observed for a period of 14 days after treatment.

Two males and three females from the 1600 mg/kg treatment group and four from each of the 2000 mg/kg and 2500 mg/kg groups died during the day of treatment. Eleven days after treatment all surviving animals were free of symptoms which had included squatting posture, sunken flanks, bristling coat, decreased

spontaneous activity, irregular respiration, stilted and uncoordinated gait, narrowed palpebral fissures and diarrhoea. In addition to these symptoms the females only showed ataxic gait, respiratory sounds, tonic clonic convulsions, prone position and straddling hind limbs. Body weight increases occurred normally. Macroscopic examination of the dead animals revealed a gas bloated and bleeding stomach, diffuse reddening of the stomach and intestinal mucosa, and general autolysis. Animals killed at the end of the observation period showed no macroscopically visible changes.

An LD<sub>50</sub> of 1250 mg/kg was calculated for the females. Due to the small male sample size and treatment at only one dose level no LD<sub>50</sub> was calculated, but results suggest a figure similar to 1250 mg/kg.

#### **9.1.2 Skin Irritation (4)**

This study was conducted in accordance with *OECD guideline No: 404* (7).

Three New Zealand albino rabbits were treated with 0.5 ml of Coupling Additive U8006 applied on a cellulose patch to the clipped skin of the dorsal region. The patch was covered with a semi occlusive bandage. After 4 hours the bandage was removed and the skin was washed. The treated area was examined 30 - 60 minutes and 24, 48, and 72 hours after removal of the patches.

Very slight to well defined erythema was observed in all animals for 2 days. Very slight oedema was observed in one animal only at 30 - 60 minutes after patch removal. The symptoms were reversible and none were apparent 3 days after removal of the skin patches.

Coupling Additive U8006 was concluded to be a moderate irritant to the skin of the rabbit.

#### **9.1.3 Eye Irritation (5)**

This study was conducted in accordance with *OECD guideline No: 405* (8).

One hundred microlitres of U8006 was applied once to the conjunctival sac of the left eye of one New Zealand albino rabbit. The untreated right eye of the rabbit was used as a control.

The eye was examined 1, 24, 48 and 72 hours after application of the substance, and since effects were still present in the eye after this time further examinations were carried out for 7 days. The treated eye was rinsed out with saline 1, 3 and 7 days after application as well as at all later designated examination times.

The conjunctivae showed deep crimson to beefy reddening and swelling to the point of the lids being half to completely closed for 7 days. Conjunctival discharge changed from clear



and colourless on day 1 to become viscous and yellow on days 2-7.

The iris was reddened over the whole 7 days and corneal opacity worsened from diffuse to opalescent where details of the iris became invisible and pupil size barely discernible. More than three quarters of the area of the cornea was affected from day 1 onwards. The conjunctivae and nictitating membranes were blanched from day 2 and 1 respectively. The nictitating membranes were observed to be exfoliating from day 3, and haemorrhage was evident on days 2 and 3. Vascularisation of the cornea was described as extreme by day 7 of the study.

The study suggests that Coupling Additive U8006 is a severe irritant to the eyes, with no evidence of irreversibility.

## **9.2 Genotoxicity**

### **9.2.1 Salmonella typhimurium Reverse Mutation Assay (9)**

The study was carried out in accordance with the *OECD Guidelines for testing of Chemicals No: 471* (10).

Coupling Additive U8006 was tested for its ability to cause gene mutations in the *Salmonella typhimurium* bacterial reverse mutation assay.

In a preliminary study concentrations of Coupling Additive U8006 of 0, 4, 20, 100, 500, 2500 or 10,000 µg per plate were tested. *S.typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 were utilised for both the preliminary and the main study. The substance was found to be very toxic to *S.typhimurium* at doses greater than or equal to 100 µg per plate without activation and 500 µg per plate with activation. As a result of this study the concentrations selected for the main study were 0, 0.16, 0.8, 4, 20, 100, or 500 µg per plate.

Positive controls were used for each strain of bacteria. In the absence of metabolic activation the controls used were sodium azide for TA100 and TA1535, 9-aminoacridine for TA1537 and 2-nitrofluorene for TA98 and TA1538. In the presence of metabolic activation benzo[a]pyrene and 2-aminoanthracene were used for all 5 strains of bacteria.

Both in the absence and presence of an Aroclor 1254 induced rat liver metabolising system, the test compound failed to produce any dose dependent increase in the number of revertants in any of the strains of *S.typhimurium*. All positive controls produced marked increases in the number of revertant colonies within the normal range.

The results indicate that Coupling Additive U8006 is not genotoxic toward *Salmonella typhimurium*.

### 9.3 Overall Assessment of Toxicological Data

Coupling Additive U8006 was found to have low acute oral toxicity to rats ( $LD_{50} = 1250$  mg/kg), and moderate dermal irritancy and severe eye irritancy to rabbits. It is not genotoxic in the *Salmonella typhimurium* reverse mutation assay.

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Environmental effects testing is not a requirement for limited polymer notifications. However, the company provided the test report (11) from static aquatic toxicity testing in zebrafish (*Brachydanio rerio*). The coupler proved moderately toxic, with a 96 h  $LC_{50}$  of 7.1 mg/L based on measured concentrations. This toxicity is not unexpected given the quaternary ammonium counter ion, as most quaternary ammonium compounds are acutely toxic to aquatic organisms in the laboratory at concentrations between 0.5 and 10 mg/L (12). However, toxicity is attenuated in the environment through sorptive interactions with particulates and dissolved organic carbon.

Data indicating the coupling agent to be practically non-toxic to sewage bacteria were also provided (13). A respiration inhibition test (OECD Test Guideline No 209) (14) on non-adapted activated sludge returned an  $EC_{50}$  of 140 mg/L.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The company has indicated that the coupler will not enter aquatic environments because of its strong sorption to insoluble pigments that must be removed from aqueous waste streams before discharge.

The company indicates that formulation of a typical batch of resinated pigments would consume 140-280 kg of the coupling additive and produce 70 m<sup>3</sup> of aqueous effluent, after filtration and washing. The maximum concentration of the coupling agent in the slurry would be 4000 ppm, but sorption to the pigment removes the bulk from solution, with residues in clarified effluent reduced below 10 ppm, even before reaching the sewer.

Even if a batch of the coupling agent were to be inadvertently flushed to sewer, dilution in the daily effluent flow through Werribee of 500 ML would leave a concentration in the order of 0.5 ppm, more than an order of magnitude below available aquatic end points, including for sewage bacteria. Given strong sorptive properties and biodegradation at these subcidal concentrations, lower concentrations would be expected to prevail, even in this hypothetical situation of discharge of the notified coupler to sewer without use. When the coupler is incorporated in insoluble resinated pigments, the possibility of significant aquatic exposure is minimal.

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

Coupling Additive U8006 is a waxy substance in its technical state and will therefore be easily contained and not easily inhaled or spilled. In its formulated state as part of a pigment, however, the notified chemical will exist as a powder. It will therefore be able to be inhaled and more easily spilled. The increased hazard presented by this formulation may be balanced by a much lower proportion of Coupling Additive U8006 being present. Although Coupling Additive U8006 is a polymer with a molecular weight over 1000, a high proportion of low molecular weight species are below 1000. These low weight components may be absorbed across biological membranes into the body.

The known toxicological properties of the notified chemical suggest that some hazard exists if exposure to Coupling Additive U8006 occurs. Animal studies suggest that contact with the eyes may result in severe and prolonged irritation and contact with the skin may cause moderate irritation. Therefore, extreme caution must be taken to avoid any eye contact during its use. There will be more opportunities for this to occur when the substance has been incorporated into the powder pigment and liquid ink when dust and splashes may result in worker contact.

Thirty production personnel workers are expected to be exposed directly to Coupling Additive U8006, largely during transferring and weighing processes. Other workers, packaging personnel and engineering fitters may be exposed directly if automatic packaging procedures are not in operation. However, with the use of adequate personal protection and good work practices there is a low risk associated with the use of Coupling Additive U8006.

The public may come into contact with the chemical in printed publications which contain inks incorporating the polymer. The polymer present in these inks will be strongly bound to the pigment and the paper. The low concentration of the polymer in the printing inks, the strong binding of the polymer to pigment particles, and the incorporation of the pigment in an ink varnish all indicate that routine exposure of the public to the chemical in printed publications will not pose a health hazard.

## **13. RECOMMENDATIONS**

To minimise occupational exposure to Coupling Additive U8006 the following guide-lines and precautions should be observed.

- . Good work practices should be implemented to avoid spillages and dust generation, and local and general ventilation provided.
- . If engineering controls and work practices are insufficient to significantly reduce exposure to a safe level, then

personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336; AS 1337) (15,16), impermeable gloves (AS 2161) (17), protective clothing (AS 3765.1 AS 3765.2) (18,19) and particulate respirator Class L or M (AS 1716) (20,21) should be worn.

- . Good personal hygiene should be adopted.
- . The single site referred to in the notification is to remain the only site for use of the technical product.
- . A copy of the MSDS for products containing Coupling Additive U8006 should be easily accessible to employees working with products containing the chemical.

#### **14. MATERIAL SAFETY DATA SHEET**

The Material Safety Data Sheet (MSDS) for Coupling Additive U8006 was provided in Worksafe Australia format (22). This MSDS was provided by Hoechst Australia Ltd 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 Hoechst Australia Ltd.

#### **15. REQUIREMENTS FOR SECONDARY NOTIFICATION**

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Coupling Additive U8006 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Given the water solubility and moderate aquatic toxicity of the coupling agent, it is particularly important from the environmental perspective that notification should be provided of any change in its function or use that may entail a significant increase in aquatic exposure. No other specific conditions are prescribed.

#### **16. REFERENCES**

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2. *Testing of Potential Biodegradability of Auxiliary U 8006*, Hoechst Report No 91 - C161-W1, January 1993 (translated from the German).
3. Hofmann and Jung, *Kupplungshilfsmittel U 8006 Testing for acute oral toxicity in the Wistar rat*, Study No. 91.0669, Report No 92.0272 May 1992, Hoechst Aktiengesellschaft.

4. Kreiling and Jung, *Kupplungshilfsmittel U 8006 Test for primary dermal irritation in the rabbit*, Study No. 91.0670, Report No. 92.0273, May 1992, Hoechst Aktiengesellschaft.
5. Kreiling and Jung, *Kupplungshilfsmittel U 8006 Test for primary eye irritation in the rabbit*, Study No. 91.0671, Report No. 92.0274, May 1992, Hoechst Aktiengesellschaft.
6. OECD Guidelines for Testing of chemicals - *Acute Oral Toxicity* No: 401, 1981.
7. OECD Guidelines for Testing of Chemicals - *Acute Dermal Irritation/Corrosion* No: 404, 1981.
8. OECD Guidelines for Testing of chemicals - *Acute Eye Irritation/Corrosion* No:405, 1987.
9. Stammberger, I *Kupplungshilfsmittel U 8006 Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test)*, Study No. 91.0668, Report No. 91.1156, November 1991, Hoechst Aktiengesellschaft.
10. OECD Guidelines for Testing of chemicals - *Salmonella typhimurium, Reverse Mutation Assay* No:471, 1983.
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12. US EPA, *Generic Assessment of Ecological Effects of Quaternary Ammonium Compounds*, Environmental Effects Branch, Health and Environmental Review Division, November 1984.
13. M Noack, *Testing for Bacterial Toxicity in Activated Sludge - Respiration Inhibition Test of Auxiliary U 8006*, Laboratorium für Angewandte Biologie, Journal Nr 2309, November 1991 (English translation November 1993).
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15. Australian Standard 1336-1982 *Eye protection in the Industrial Environment*, Standard Association of Australia Publ., Sydney, 1982.
16. Australian Standard 1337-1984 *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.
17. Australian Standard 2161-1978 *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.
18. 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, 1990.

19. Australian Standard 3765.2-1990 *Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals*. Standards Association of Australia Publ., Sydney, 1990.
20. Australian Standard 1715- 1991 *Selection, use and maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, 1991.
21. Australian Standard 1716-1991 *Respiratory Protective Devices*, Standards Association of Australia Publ., Sydney, 1991.
22. National Occupational Health and Safety Commission, *Guidance Note for Completion of a Material Safety Data Sheet*, 3rd Edition, Australian Government Publishing Service Publ., Canberra, 1991.